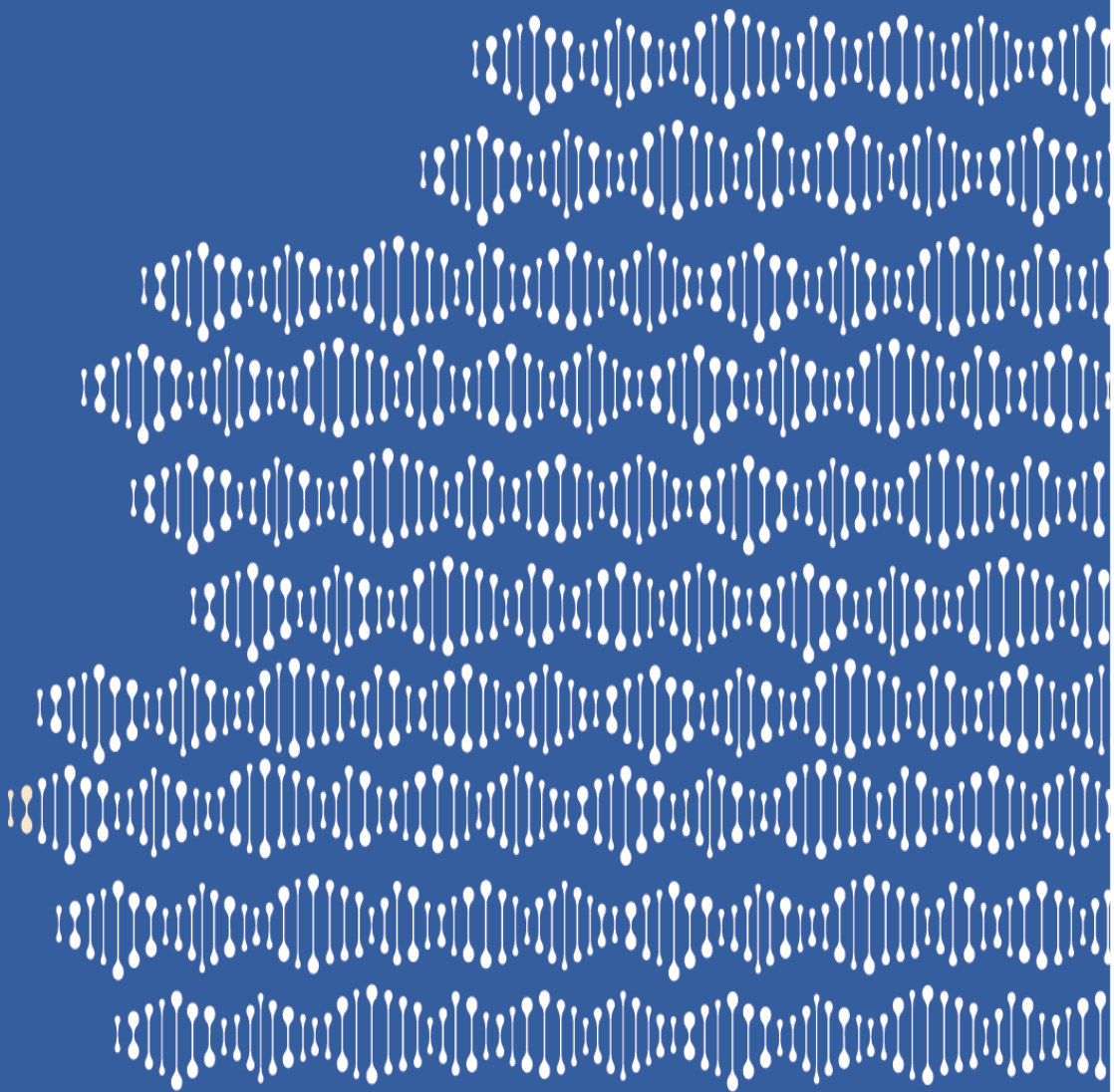
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

February 19, 2025



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Summary Overview of the February 19, 2025, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the February 19, 2025, Oversight Committee meeting.

Grantee Presentation
Dr. Laura Indolfi, CEO of PanTher Therapeutics, will present a progress overview since receiving a CPRIT Product Development Research grant (DP220066) to support the project "Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer" in August 2022.

CEO Report
Kristen Doyle will present the CEO's report and address issues including FY 2025 grant funds available, CPRIT's 2024 Annual Report, personnel and agency employment level, the 89th Legislative Session, and other topics. Ms. Doyle will also present her annual report required by Tex. Health & Safety Code § 102.260(c).

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews, site visits, annual compliance attestation, audit tracking, and training. He will also certify that the proposed awards for the academic research program complied with statutory and administrative rule requirements.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. Michelle Le Beau will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) academic research and recruitment award recommendations.

CPRIT does not publicly disclose information related to the academic research grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention Officer Report
Ramona Magid will update the Oversight Committee on the Prevention Program.

Chief Product Development Officer Report
Dr. Ken Smith will provide an update on the Product Development Research Program and will present the four proposed product development RFAs for FY 2026.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will present an internal audit update.

Appointments - Scientific Research and Prevention Programs Committee
Ms. Doyle has provisionally appointed six new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to finalize the appointments with votes of approval. CPRIT has provided the appointees' biographical sketches for the Oversight Committee's consideration.

Advisory Committee Appointments and Annual Presentations

- Presiding Officer Dr. David Cummings has provisionally appointed three new members to CPRIT's Advisory Committees. CPRIT's statute requires the Oversight Committee to finalize the appointments with votes of approval. CPRIT has provided the appointees' biographical sketches for the Oversight Committee's consideration.
- The Advisory Committee on Childhood Cancer will present their annual report and answer questions from the Oversight Committee.

Proposed Amendments to 25 TAC Chapter 703
Cameron Eckel will present the final order approving changes to the agency's Chapter 703 administrative rules for the Oversight Committee's consideration. The Oversight Committee provisionally approved the changes at its November 2024 meeting.

Chief Financial Officer Report
Grant Weaver will discuss the operating budget, performance measures, and debt issuance history for the first quarter of FY 2025.

CPRIT Innovations VII Conference
Heidi McConnell will provide a planning update for the CPRIT conference.

Communications Update
Mark Loeffler will update the Oversight Committee on CPRIT's communication efforts, including coverage of the agency and grantees in earned media, digital media, and social media and the FY 2024 annual report.

Health & Safety Code Section 102.255(d) and Supplemental Guidance to the 2024 NIH Grant Policy Statement: Indirect Cost Rates
The National Institutes of Health recently issued supplemental guidance regarding federal indirect cost rates. John Ellis will separately provide legal advice regarding the potential impact to academic research grantees' matching funds obligation.

Proposed Board Retreat
Presiding Officer Dr. Cummings will provide an update on plans for an upcoming Oversight Committee Board Retreat.

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Agenda

February 19, 2025
8:30 a.m.

The Barbara Jordan Building
1601 Congress Avenue, Austin, TX 78701
Room 2.035A

The Oversight Committee may discuss or act on any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purpose permitted by the Act. If the Oversight Committee meets in closed session, it will do so in the Barbara Jordan Building, Room 2.027.

Also as authorized by Texas Government Code § 551.127, one or more Oversight Committee members may participate remotely in the meeting by videoconference. The Oversight Committee member presiding over the meeting will be physically present at the above-listed location, which will be open to the public.

Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of November 20, 2024, Meeting Minutes — Tab 1
4. Public Comment
5. Grantee Presentation — Tab 2
6. Chief Executive Officer Report — Tab 3
   - State Agency Employment Level
   - CEO Report Pursuant to Health & Safety Code § 102.260(c)
7. Chief Compliance Officer Report and Compliance Certification of Grant Award Process — Tab 4
8. Chief Scientific Officer Report — Tab 5
   - Grant Award Recommendations
9. Chief Prevention Officer Report — Tab 6
10. Chief Product Development Officer Report — Tab 7
    - FY 2026 Requests for Applications
11. Internal Auditor Report — Tab 8
12. Scientific Research and Prevention Program Committee Appointments — Tab 9
13. Advisory Committees — Tab 10
    - Advisory Committee Appointments
    - Advisory Committee on Childhood Cancer Presentation
14. Amendments to 25 T.A.C. Chapter 703 — Tab 11
    - Amendments to Chapter 703 – Final Order

15. Chief Financial Officer Report Tab 12
16. CPRIT Innovations VII Conference Tab 13
17. Communications Program Update Tab 14
18. Health & Safety Code Section 102.255(d) and Supplemental Guidance to the 2024 NIH Grant Policy Statement: Indirect Cost Rates
19. Subcommittee Business
20. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
21. Consultation with General Counsel
22. Future Meeting Dates and Agenda Items
    - Proposed Board Retreat
23. Adjourn

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Minutes
November 20, 2024

NOTE: Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available at http://ocmeetings.cprit.texas.gov in the "Oversight Committee Board Packet" section for the corresponding meeting date.

Call to Order – Agenda Item 1

Presiding Officer Dr. David Cummings announced a quorum present and called the meeting to order at 8:31 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present
David Cummings, M.D.
Ambrosio Hernandez, M.D.
Donald (Dee) Margo
Will Montgomery
Cindy Barberio Payne
Bill Rice, M.D.
Craig Rosenfeld, M.D.
Thomas (Tommy) Taylor

Committee Members Absent
Mahendra Patel, M.D., P.A.

Presiding Officer Dr. Cummings noted that Dr. Patel previously notified CPRIT staff that he would be unable to attend today's meeting.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee members voted unanimously to approve Dr. Patel's absence.

Adoption of Minutes from the August 21, 2024, and September 25, 2024, Meetings – Agenda Item 3

MOTION:
On a motion by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the minutes of the August 21, 2024, and September 25, 2024, Oversight Committee meetings as presented.

Public Comment – Agenda Item 4

Presiding Officer Dr. Cummings noted for the record that no member of the public asked to provide comments.

Chief Executive Officer Report – Agenda Item 5, Tab 2

Presiding Officer Dr. Cummings recognized Chief Executive Officer Kristen Doyle to present her report.

Ms. Doyle reminded members that CPRIT approved its first grant 15 years ago. She introduced the three new staff members who have joined CPRIT since the August meeting. Ms. Doyle reviewed CPRIT's budget request that the Texas Legislature will consider in the upcoming 2025 session. She ended her report by addressing agenda item 17. She explained that CPRIT has exceeded its FTE cap. She noted that she has notified state leadership of the issue.

Chief Compliance Officer Report and Compliance Certification for the Proposed Grant Awards – Agenda Item 6, Tab 3

Presiding Officer Dr. Cummings recognized Compliance Program Manager Stephen Nance to present the compliance report.

Following his presentation, an Oversight Committee member asked what happens when CPRIT identifies unallowable match expenses. Mr. Nance responded that CPRIT removes all unallowable expenses from the grantees match expense total for that year.

Mr. Nance presented the Chief Compliance Officer's Compliance Certification on behalf of Mr. Burgess for the proposed academic research, prevention research, and product development grant awards, confirming that the proposed awards and review process complied with all applicable state and agency requirements.

There were no questions for Mr. Nance following the Compliance Certification presentation.

Chief Prevention Officer Report and Grant Recommendations – Agenda Item 7, Tab 4

Presiding Officer Dr. Cummings recognized Chief Prevention Officer Ramona Magid to provide the Prevention program update.

Ms. Magid presented her Prevention report, the FY2026 RFAs, and the grant recommendations.

The three proposed FY 2026 RFAs include:

- Cancer Screening and Early Detection,
- Primary Prevention of Cancer, and
- Dissemination of CPRIT-Funded Cancer Control Interventions.

In response to an Oversight Committee member's question about additional methods to measure the impact of the prevention program, Ms. Magid said that the program measures the impact with metrics such as screenings, diagnostics, and cancerous precursors and cancers detected. She noted that CPRIT's Economic Assessment of Cancer in Texas annual report includes the economic impact of the Prevention program.

An Oversight Committee member asked if cancer screenings are available in every county. Ms. Magid explained that CPRIT prevention projects serve residents of every county in Texas.

Following the questions, Ms. Magid provided an overview of Cycle 25.1 recommended awards, comprising three slates of eight recommended awards totaling $13.4 million. Ms. Magid reported that all applications address one or more of the Prevention Program priorities.

Prevention Award Recommendations
Cycle 25.1

CSD: Cancer Screening and Early Detection
DI: Dissemination of CPRIT-Funded Cancer Control Interventions
PPC: Primary Prevention of Cancer

Rank	App. ID	Mech.	Application Title	PD	Organization	Budget	Final Score
1	PP250006	CSD	Expansion of Cancer Screening and Early Detection Services to Rural & Medically Underserved Communities	Duckworth, Jessica	The Rose	$2,500,000	2.7
2	PP250019	CSD	Saved by the Scan: Lung Cancer Screening and Patient Navigation in East Texas	Argenbright, Keith	The University of Texas Southwestern Medical Center	$1,499,243	3.1
3	PP250016	PPC	Screening and treatment for unhealthy alcohol use for cancer prevention in Central Texas – 2	Calderon-Mora, Jessica	The University of Texas at Austin	$1,000,000	3.4
4	PP250046	CSD	The Houston Prevenir, Ayudar, Poder (PAP) Project	Zamorano, Abigail	The University of Texas Health Science Center at Houston	$1,499,997	3.6
5	PP250004	CSD	A Virtual, Centralized Lung Cancer Screening Program for Northeast Texas	Minnix, Jennifer	The University of Texas M. D. Anderson Cancer Center	$1,497,342	3.7
6	PP250009	CSD	The Central Texas Colorectal Cancer Screening Program (CTX-CCSP)	Shokar, Navkiran	The University of Texas at Austin	$2,500,000	3.8
7	PP250018	DI	Texas Comprehensive Access & Resources for Early Lung Cancer Prevention (TEX-CARE)	Zoorob, Roger	Baylor College of Medicine	$449,929	3.8

Prevention Award Recommendations Cycle 25.1 *CSD: Cancer Screening and Early Detection* *DI: Dissemination of CPRIT-Funded Cancer Control Interventions* *PPC: Primary Prevention of Cancer*							
8	PP250005	CSD	Project 80% Colorectal Cancer Screening Program	Foxhall, Lewis	The University of Texas M. D. Anderson Cancer Center	$2,499,990	4.2

Responding to an Oversight Committee member's question, Ms. Magid confirmed that the dissemination project would be available in Spanish to addresses bilingual needs.

An Oversight Committee member asked about follow-up after an abnormal screening test. Ms. Magid explained that CPRIT requires all grantees to navigate patients to diagnostic testing and, if necessary, into treatment.

In response to an Oversight Committee member's question, Ms. Magid explained that UT Austin patients receive follow-up care at Dell Medical Center.

An Oversight Committee member asked about the available blood screening test for colorectal cancer. Ms. Magid responded that grantees may propose the use of this screening method in their applications but have not yet done so. She noted that at the most recent Prevention Advisory Committee (PAC) meeting, a PAC member who is an experienced clinician indicated that the blood test's specificity is very low for detecting early-stage cancers.

Texas Cancer Plan

Presiding Officer Dr. Cummings recognized CPRIT Prevention Program Manager Carlton Allen to present the Texas Cancer Plan (TCP) 2024.

Following his presentation, an Oversight Committee member asked if the previous version of the TCP is available in print format. Mr. Allen stated it was, but the TCP 2024 version is online only. This will allow for updates before the release of the next version.

An Oversight Committee member asked if the TCP 2024 contained the most current data. Mr. Allen explained that the Texas Cancer Registry provided the data for the TCP 2024. COVID's impact on screening, early detection, morbidity, and mortality may skew some numbers for the 2022-2024 period, or the data is unavailable.

In response to an Oversight Committee member's question about county level data, Mr. Allen noted that the map shows data at the Public Health Region level. The data for many counties in Texas is suppressed due to the small numbers of cancer cases or deaths.

An Oversight Committee member asked if the TCP 2024 includes target metrics. Mr. Allen noted that the TCP 2024 incorporates current baseline and target metrics and comparisons with national rates. The Department of State Health Services will evaluate the Plan mid-cycle.

Mr. Allen acknowledged CPRIT Technical Writer Bridget Barstow's assistance in writing the TCP 2024.

Dr. Cummings and the Oversight Committee members thanked Mr. Allen for the presentation.

APPROVAL PROCESS – Prevention Awards

Compliance Certification & Conflict of Interest Notifications

Presiding Officer Dr. Cummings reminded members that Mr. Burgess previously certified that the prevention award process complied with all applicable requirements. He noted that no Oversight Committee members reported conflicts of interest with the proposed awards.

Approval of Prevention Awards

Presiding Officer Dr. Cummings noted that there are eight prevention award recommendations. Rather than taking a separate vote on each grant application, the Oversight Committee members voted to approve all the recommendations in one motion.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee voted unanimously to approve the PIC's eight recommendations for the following prevention grant award mechanisms:

- Cancer Screening and Early Detection,
- Primary Prevention of Cancer, and
- Dissemination of CPRIT-Funded Cancer Control Interventions.

Delegation of Contract Negotiation and Execution Authority

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve delegating contract negotiation authority to the CEO and CPRIT staff and to authorize the CEO to sign the contracts on behalf of CPRIT.

Approval for FY2026 RFAs

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee voted unanimously to approve the three proposed FY 2026 Cycle 1 RFAs.

Prevention Advisory Committee Report - Item 12, Tab 9

Presiding Officer Dr. Cummings noted that the Committee will hear the Prevention Advisory Committee report from Agenda Item 12, Tab 9, out of order.

Ms. Magid introduced Prevention Advisory Committee Chair Dr. Navkiran Shokar, professor and chair of the Department of Population Health and associate dean for Community Affairs at Dell Medical School at The University of Texas at Austin, to present the Prevention Advisory Committee report.

Following Dr. Shokar's report, an Oversight Committee member noted that obesity is a major, world-wide problem, with the obesity problem in adolescents getting worse and acknowledged that not everyone has the same resources. Dr. Shokar responded that obesity is a multifactorial and complicated problem, and we all need to come together to tackle the enormous problem. It will be a big job ahead for the cancer prevention and research community, as well as the policy makers and stakeholders.

An Oversight Committee member asked if the 40,000 cancer precursors detected from the screening outcomes meant that the patients would develop cancer or just have a proclivity to develop cancer. Dr. Shokar stated that it depends on the cancer; cervical cancer and colorectal cancer are the ones that we know best, but not all of those will move on to cancer. However, a good majority of those will.

An Oversight Committee member commented about late-stage cancers. Dr. Shokar stated that the goal of early detection programs is to shift from detecting late-stage cancer to finding it at earlier stages. Late-stage cancer often has symptoms, but not always. Symptoms can be very vague, and this is particularly a problem in younger people.

An Oversight Committee member commented that the incidence of hepatocellular carcinoma is especially high in the Rio Grande Valley and questioned if doctors should screen for toxic materials in exposed people, as opposed to the screening for cancer. Dr. Shokar responded that a cost/benefit analysis and determining which environmental exposures can lead to cancer are necessary. More research is necessary to identify and target the exposure types with maximum association to cancer. Not everyone exposed to toxins will get cancer. The cancer care community needs to consider resource needs and how effective a test like that might be. Dr. Shokar also noted that researchers must look at the data to assess the attributable risk, such as in cervical cancer, which is frequently caused by HPV.

Presiding Officer Dr. Cummings thanked Dr. Shokar for the presentation on behalf of the Oversight Committee.

Chief Scientific Officer Report – Agenda Item 8, Tab 5

Presiding Officer Dr. Cummings recognized Chief Scientific Officer Dr. Michelle Le Beau to provide the Academic Research Program update, including the proposed FY 2026 RFAs, and to introduce the Program Integration Committee's Grant Award recommendations.

Dr. Le Beau presented her program update and the FY 2026, cycle 1 RFAs:

- Individual Investigator Research Awards

- Individual Investigator Research Awards for Computational Systems Biology of Cancer
- Individual Investigator Research Awards for Cancer in Children and Adolescents
- Individual Investigator Research Awards for Prevention and Early Detection
- Individual Investigator Research Awards for Clinical Trials
- Individual Investigator Research Awards for Early-Onset Cancers

Following her program update, Dr. Le Beau presented the Program Integration Committee award recommendations for the FY2025 Recruitment Cycle 1. The five recruitment grant proposals total $12,000,000.

Academic Research Award Recommendations
Recruitment Cycle 25.1
RFTFM: Recruitment of First-Time, Tenure-Track Faculty Members
RRS: Recruitment of Rising Stars

Rank	App. ID	Mech.	Application Title	PI	PI organization	Budget	Final score
1	RR250017	RFTFM	Targeting Membrane Enzymes by Structure-Based Drug Discovery for Pancreatic Ductal Adenocarcinoma	Fangyu Liu, Ph.D.	The University of Texas Southwestern Medical Center	$2,000,000	1.0
2	RR250052	RFTFM	Harnessing Protein Translation Machinery to Overcome Resistance of KRAS Inhibitors	Xiangdong Lv, Ph.D.	The University of Texas Health Science Center at Houston	$2,000,000	1.0
3	RR250002	RFTFM	Dissecting Niche Cells in Cancer Immunity and Metastasis	Norihiro Goto, M.D., Ph.D.	The University of Texas MD Anderson Cancer Center	$2,000,000	1.1
4	RR250014	RFTFM	Decoding the Immune Network Dynamics in Acute Myeloid Leukemia	Xufeng Chen, Ph.D.	The University of Texas MD Anderson Cancer Center	$2,000,000	1.1
5	RR250048	RRS	Novel clinical biomarkers and mechanisms of Cardiotoxicity	Daniel Addison, M.D.	The University of Texas Southwestern Medical Center	$4,000,000	1.1

Following her presentation, no Oversight Committee members raised questions regarding the proposed FY 2026 RFAs and the award recommendations.

APPROVAL PROCESS – Academic Research Awards

Compliance Certification & Conflict of Interest Notifications

Presiding Officer Dr. Cummings reminded members that Mr. Burgess previously certified that the academic research program award process complied with all applicable requirements. He noted for the record that no member reported a conflict of interest with any recruitment awards.

Approval for Academic Research Awards

Presiding Officer Dr. Cummings noted that rather than taking a separate vote on each of the five proposed recruitment awards, he will take one vote to approve all five recommendations.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the PIC's five recommendations for the Recruitment of Rising Stars and Recruitment of First-Time, Tenure-Track Faculty Members academic research grant award mechanisms.

Delegation of Contract Negotiation and Execution Authority

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee voted unanimously to approve delegating contract negotiation authority to the CEO and CPRIT staff and to authorize the CEO to sign the contracts on behalf of CPRIT.

Approval for Proposed FY 2026 RFAs

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the six proposed FY 2026, cycle 1 RFAs.

Chief Product Development Officer Report and Grant Recommendations – Agenda Item 9, Tab 6

Presiding Officer Dr. Cummings recognized Chief Product Development Officer Dr. Ken Smith to present the product development program update, proposed FY 2025 RFAs, and the grant recommendations.

Dr. Smith presented the product development program update, the proposed FY 2025 Competitive Cost Adjustment RFA, and the grant recommendations.

Product Development Research Recommendations
Cycle 25.1
SEED: SEED Awards for Product Development Research
TDDC: Texas Diagnostic and Devices Company Awards
TTC: Texas Therapeutics Company Awards

Rank	ID	RFA	Company	Project	Score	Budget
1	DP250157	TDDC	Curve Biosciences	Clinical Utility Study for the Commercial Launch of a Best-in-Class Liver Cancer Screening Blood Test for High-Risk Liver Disease Patients	1.9	$11,340,000

Product Development Research Recommendations Cycle 25.1 *SEED: SEED Awards for Product Development Research* *TDDC: Texas Diagnostic and Devices Company Awards* *TTC: Texas Therapeutics Company Awards*						
2	DP250150	TTC	Marker Therapeutics, Inc.	A Phase 1 Study of Multi-Tumor Associated Antigen Specific T Cells (MT-601) in Patients with Metastatic Pancreatic Cancer following frontline FOLFIRINOX	2.1	$9,513,569
3	DP250143	SEED	Telos Biotechnology	TELOVANCE: A Transient Telomere Lengthening Platform Designed to Enhance the Expansion and Efficacy of Human Cell and Gene Therapies	2.3	$2,778,945
4	DP250135	TTC	Metaclipse Therapeutics Corporation	Personalized Immunotherapy for Recurrent, Resectable Head and Neck Cancer	2.4	$6,080,245
5	DP250159	TTC	Barricade Therapeutics, Corp.	(S)-TASIN-15 Phase 1 Dose Escalation, Optimization & RP2D Determination	2.4	$14,005,035
6	DP250137	SEED	Ypsilon Therapeutics	Revolutionizing Solid Tumor Therapy with Bispecific TCRm Antibodies Targeting Intracellular Cancer Targets	2.5	$2,727,500
7	DP250140	TTC	Orphagen Pharmaceuticals Inc.	A Phase 1 clinical trial of OR-449, a novel oral targeted therapy for pediatric and adult adrenocortical cancer patients	2.6	$10,213,909
8	DP250142	TTC	Eisbach Bio, Inc.	Eisbach Bio - Clinical Development of the ALC1 DDR inhibitor EIS-12656	2.7	$4,750,000
9	DP250149	SEED	Erisyon, Inc.	Functional assay of immunoproteasome for patient stratification to checkpoint inhibitor therapy using single-molecule protein sequencing	2.8	$2,157,173
TOTAL						**$63,566,376**

An Oversight Committee member asked whether product development grants include relocation expenses. Dr. Smith responded that CPRIT does not pay relocation costs.

An Oversight Committee member commented on the excellent review process and thought it was helpful for the applicants and awardees. Dr. Smith said that he thinks this process is important, even for those companies that CPRIT does not fund, because the process helps companies craft better applications if they apply for CPRIT grants in the future.

An Oversight Committee member asked if the Competitive Cost Adjustment RFA will impact royalty amounts in the award contract. Dr. Smith responded that it would not.

An Oversight Committee member asked whether reducing the award size affects the revenue share. Dr. Smith answered that it does not.

APPROVAL PROCESS – Product Development Research Awards

Compliance Certification & Conflict of Interest Notifications

Presiding Officer Dr. Cummings reminded members that Mr. Burgess previously certified that the product development award process complied with all applicable requirements. He noted for the record that Oversight Committee member Dr. Rosenfeld reported a conflict of interest with application DP250159. He instructed members that the Oversight Committee would vote first on application DP250159 before voting on the rest of the award slate as whole.

MOTION:
On a motion made by Mr. Margo, and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve DP250159.

Presiding Officer Dr. Cummings noted for the record that Dr. Rosenfeld recused himself and did not vote DP250159 due to a conflict of interest.

MOTION:
On a motion made by Mr. Montgomery, and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the PIC's remaining eight grant recommendations for the following Product Development Research grant applications: DP250137, DP250143, DP250149, DP250157, DP250135, DP250140, DP250142, and DP250150.

Delegation of Contract Negotiation and Execution Authority

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve delegating contract negotiation authority to the CEO and CPRIT staff and to authorize the CEO to sign the contracts on behalf of CPRIT.

Authorization to Disburse Grant Funds by Advance Payment

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, pursuant to the General Appropriations Act, Article IX, Section 4.02(a), the Oversight Committee voted unanimously to authorize CPRIT to disburse grant funds via advance payments upon execution of the award contract and the successful completion of tranches to the nine companies approved for awards today.

Approval for FY2025 RFA

MOTION:

On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the proposed Competitive Cost Adjustment RFA.

Ms. Doyle added for the record that in the original PIC recommendation letter there were two product development award recommendation amounts that ended in cents, which CPRIT does not use. After submitting the PIC recommendation letter, CPRIT rounded up those numbers and updated the numbers. Therefore, the overall grant funding for the nine product development awards is one dollar higher than the amount reported to and approved by PIC. The committee acknowledged the information.

FY2026 Program Priorities - Agenda Item 10, Tab 7

Presiding Officer Dr. Cummings recognized Ms. Doyle to present the staff recommendations for CPRIT's Program Priorities for the fiscal year 2026.

MOTION:
On a motion made by Dr. Rice, and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the fiscal year 2026 program priorities.

Scientific Research and Prevention Program Committee Appointments– Item 11, Tab 8

Presiding Officer Dr. Cummings recognized Ms. Doyle to present her appointments to the Scientific Research and Prevention Program Committees.

Ms. Doyle presented two appointments to the Product Development peer review panels, Bruce S. Thomson, Ph.D., and Stergios Zacharoulis, M.D.

MOTION:
On a motion made by Mr. Margo, and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the CEO's two appointments to the Scientific Research and Prevention Program Committees.

Advisory Committees - Agenda Item 12, Tab 9

Presiding Officer Dr. Cummings asked Dr. Le Beau to introduce Min H. Kang, PharmD, to present the Geographic Diversity Advisory Committee report.

Following the report, an Oversight Committee member noted that some people in north Texas approached the member regarding participation in the TREC grants. The member asked Dr. Kang if she thinks CPRIT is doing enough to provide smaller centers with CPRIT opportunities. Dr. Kang responded that CPRIT was not wasting the money invested in the geographically diverse regions. The initial investment depends on the growth and success of the larger centers and will have a bigger bang for the vision.

In response to an Oversight Committee member's question about Texas A&M Amarillo's representation on these committees, Dr. Kang explained that Amarillo is part of the Texas A&M System and benefits through this representation on the advisory committee.

An Oversight Committee member asked if CPRIT had awarded a CPRIT Scholar grant to any institution in West Texas. Dr. Kang responded that the Texas Tech University School of Veterinary Medicine and Texas Tech University Health Science Center received awards. She was not able to recall others at the moment, but it is likely that there are more.

Presiding Officer Dr. Cummings thanked Dr. Kang and the advisory committee for the presentation.

Health & Safety Code § 102.1062 Waivers – Agenda Item 13, Tab 10

Presiding Officer Dr. Cummings recognized Ms. Doyle to present the conflict-of-interest waiver for John Ellis, CPRIT's general counsel.

> **MOTION:**
> On a motion by Mr. Margo and seconded by Mr. Taylor, the Oversight Committee voted unanimously to approve the proposed Health and Safety Code Section 102.1062 waiver for Mr. Ellis.

Amendments to 25 T.A.C. Chapter 703 – Agenda Item 14, Tab 11

Presiding Officer Dr. Cummings recognized Assistant General Counsel Cameron Eckel to discuss the proposed administrative rule changes to TAC §§ 703.13(b), 703.26(b), and 703.26(e).

> **MOTION:**
> On a motion by Mr. Margo and seconded by Mr. Taylor, the Oversight Committee voted unanimously to publish the proposed changes to Texas Administrative Code Chapter 703 in the *Texas Register.*

Chief Operating Officer Report – Agenda Item 15, Tab 12
Contract Approvals - Agenda Item 16, Tab 13

Presiding Officer Dr. Cummings recognized Deputy Executive and Chief Operating Officer Heidi McConnell to present agenda items 15 and 16.

Ms. McConnell introduced the newly appointed Chief Financial Officer Grant Weaver, before presenting her report regarding the FY 2024 Quarter 4 information for the operating budget, performance measures, and debt issuance history.

<u>Contract Approvals and Extensions</u>

Ms. McConnell presented the recommended contract with Innovation Event Management, LP for conference planning and coordinating services.

MOTION:

On a motion by Dr. Rosenfeld and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the contract with Innovation Event Management, LP, for conference planning and coordinating services.

State Agency Employment Level – Agenda Item 17, Tab 14

Ms. Doyle addressed agenda item 17 previously in her CEO report.

Personnel – Chief Scientific Officer – Agenda Item 18, Tab 15

Presiding Officer Dr. Cummings recognized Ms. Doyle to present her recommendation regarding the proposed Chief Scientific Officer's salary adjustment.

MOTION:
On a motion by Mr. Taylor and seconded by Dr. Rice, the Oversight Committee voted unanimously to approve to set the exempt salary for the Chief Scientific Officer position to the legislatively authorized $671,300 effective on or after December 1, 2024.

Communication Report – Agenda Item 19, Tab 16

Presiding Officer Dr. Cummings recognized Communications Director Mark Loeffler to present his report. Mr. Loeffler updated the committee members on communications activities, including the Texas Cancer Plan.

An Oversight Committee member asked if CPRIT could generate a QR code for the Texas Cancer Plan 2024 to help disseminate the information more easily. The member also asked if CPRIT could put the TCP 2024 out to the media. Mr. Loeffler responded that when CPRIT publishes the Plan in December, we will send out a notification with the link specifically to the legislators' inboxes. CPRIT will also publish a press release, send a notification to stakeholders throughout the state government who have helped develop it, and publish the TCP 2024 on our website.

An Oversight Committee member asked if there would be a CPRIT booth or day during the legislative session. Ms. Doyle responded that we may not have CPRIT day but many advocate groups will have cancer days where they talk about what CPRIT has done and would like the legislature to continue to support CPRIT. Ms. Doyle said that CPRIT conducts more of the outreach directly with legislators and their staff.

Internal Audit Report – Agenda Item 20, Tab 17

Presiding Officer Dr. Cummings recognized Daniel Graves, representing CPRIT's internal auditor Weaver & Tidwell, to give the Internal Auditor's Report. Mr. Graves updated the

committee members on the FY 2025 Internal Audit Plan schedule.

Presiding Officer Dr. Cummings noted that the Oversight Committee would not consider standing agenda items 21, 22, or 23.

Future Meeting Dates and Agenda Items – Agenda Item 24

Presiding Officer Dr. Cummings directed members to the FY 2025 schedule for Oversight Committee and standing subcommittee meetings behind tab 18 and reminded members that the next regular Oversight Committee meeting will take place on February 19, 2025.

Adjournment – Agenda Item 25

> **MOTION:**
> There being no further business, the Oversight Committee voted unanimously to approve Presiding Officer Dr. Cummings's motion to adjourn, which Dr. Rosenfeld seconded.

Presiding Officer Dr. Cummings adjourned the meeting at 11:47 a.m.

_____ _____

Signature Date

PANTHER THERAPEUTICS

Laura Indolfi, PhD, is Co-Founder and Chief Executive Officer. Based on foundational technology she invented in the labs at Massachusetts Institute of Technology (MIT) and Harvard Medical School, she has led PanTher's business and scientific progress to create its proprietary Sagittari™ drug-development platform, a revolutionary technology for the local administration of cancer therapeutics to treat solid tumors.

Under her leadership, the company has advanced its lead drug candidate, PTM-101, from preclinical R&D studies to clinical trials for the treatment of pancreatic cancer. Dr. Indolfi has raised equity and grant funding for PanTher since its inception in 2016 and built an experienced leadership team to guide the company's success.

Dr. Indolfi has been recognized for her entrepreneurial accomplishments by being named a TED Fellow, one of 21 people chosen annually as the most disruptive and transformative change-makers in the world. Prior to founding PanTher Therapeutics, Dr. Indolfi was a postdoctoral associate at the Harvard-MIT Institute for Medical Engineering and Science and served as an entrepreneur-in-residence at the Massachusetts General Hospital Cancer Center.

She holds a PhD in Biomaterials and MS and BS degrees in Materials Science and Engineering from the University of Naples Federico II in Italy.

Austin-based PanTher received a $14.27 million Product Development Relocation grant (DP220066) in August, 2022 to support their project, "Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer."

PANTHER THERAPEUTICS

A QUANTUM LEAP FORWARD
in the fight against cancer

CPRIT Oversight Committee

February 19, 2025

Laura Indolfi, CEO – lindolfi@panthertx.com

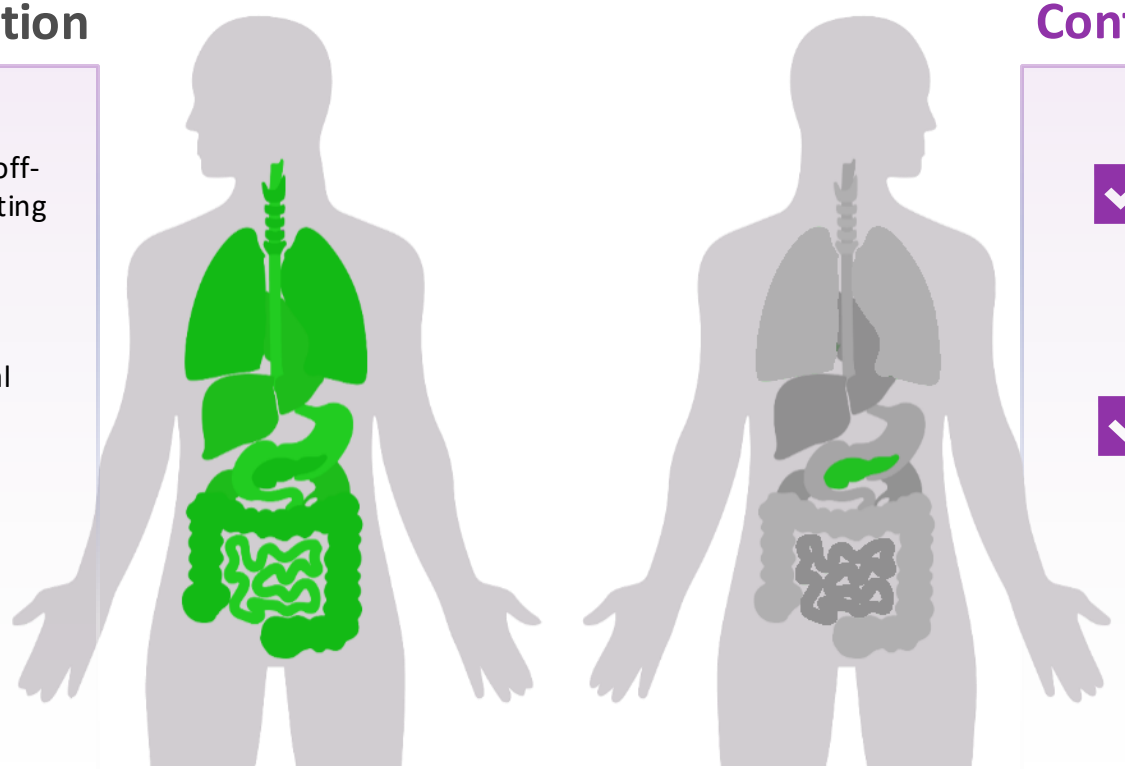
2022 Relocation Grant:
DP220066 - PanTher Therapeutics

Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents

PanTher's Platform Technology:
Addressing a Significant Clinical Challenge in the Treatment of Cancer

Traditional
Bolus Systemic Administration

- ☒ Systemic delivery of chemotherapy to off-target tissues often results in dose limiting toxicity, which minimizes a drugs effectiveness.
- ☒ Oral, IV, or SC dosing further limits total drug exposure at the tumor site due to intermittent bolus administration and short half-life.

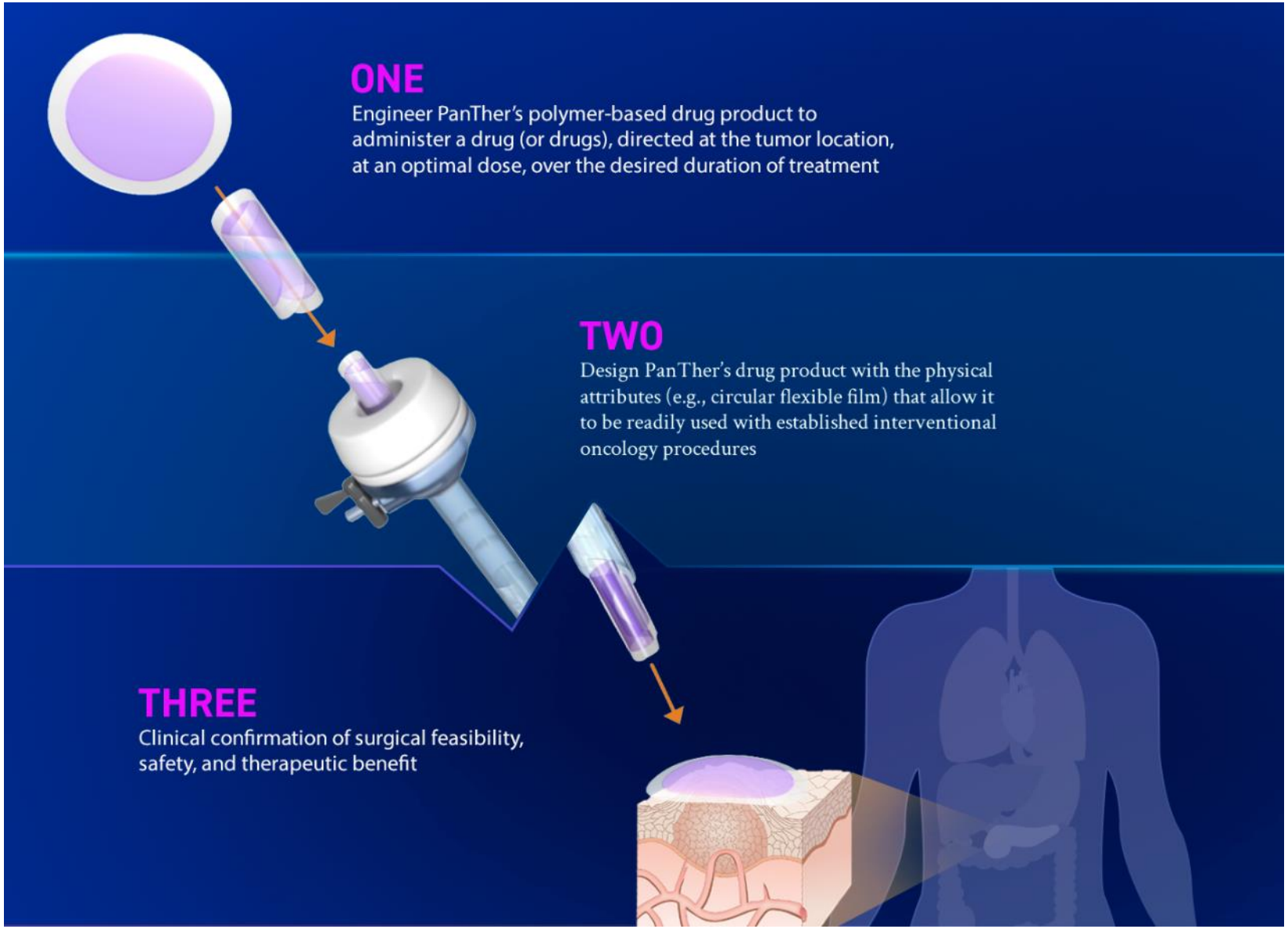


PanTher's
Continuous Local Administration

- ☑ Exclusive local delivery of chemotherapy limits systemic toxicity, enabling substantially higher drug concentrations to the tumor site (>100 fold higher than conventional chemotherapy).
- ☑ Sagittari™ dosage form offers continuous administration over weeks to months, resulting in unprecedented tumor exposure to the drug.

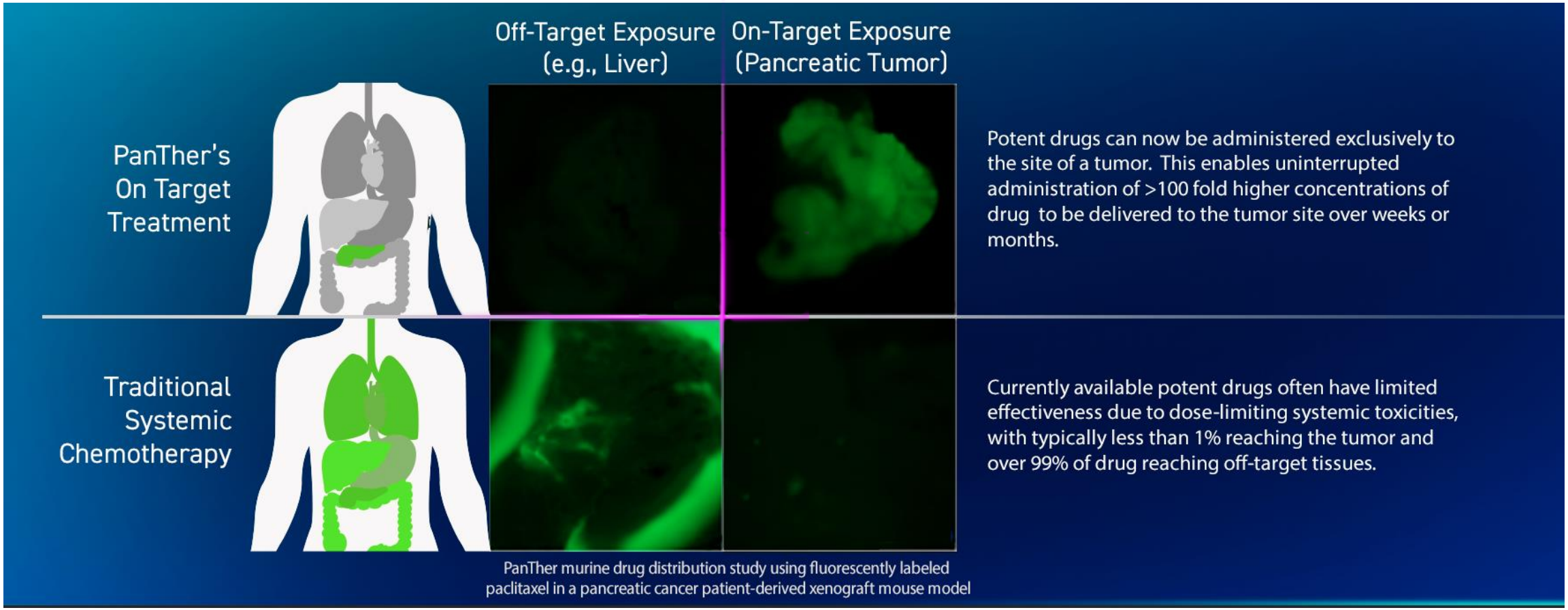
PANTHER

PanTher:
Continuous, High-Dose, Localized Cancer Treatments

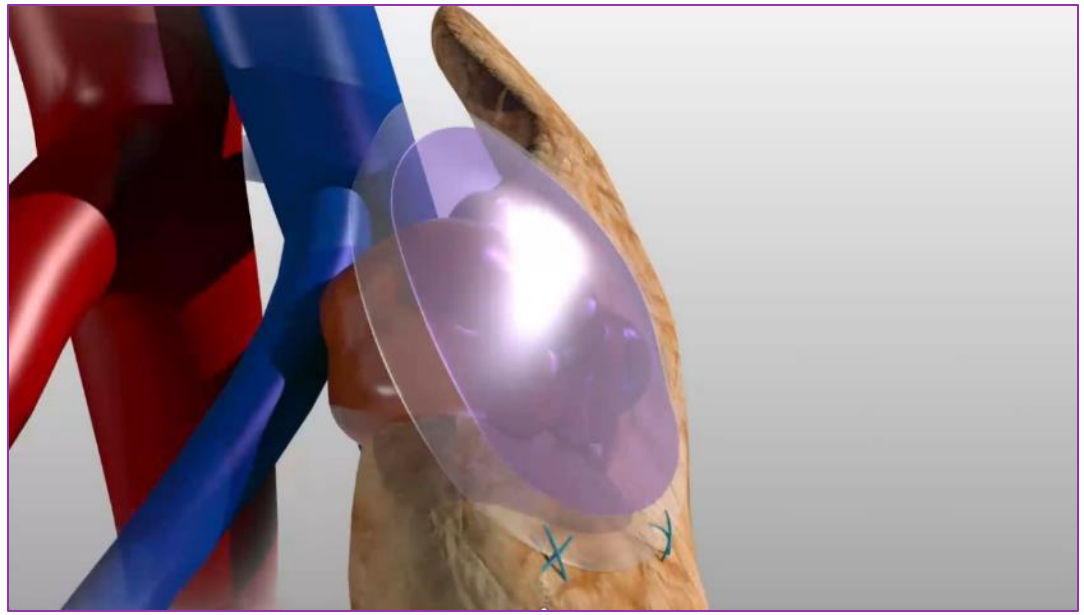


2-5

Transforming Potent Drugs into Powerful Localized Treatments

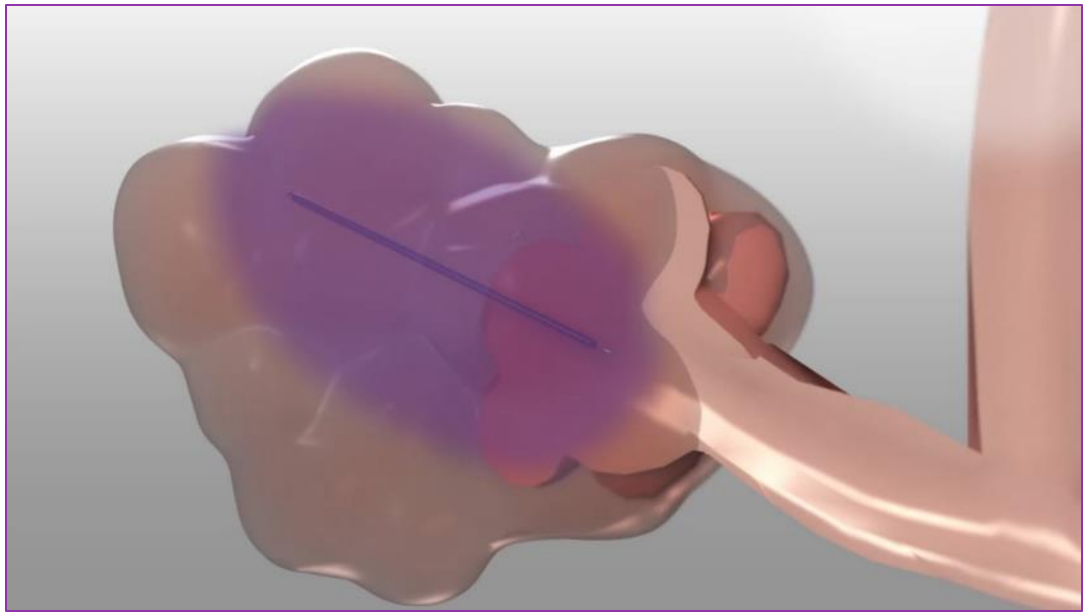


PanTher's Technology Platform: Tailored to the Needs of a Broad Range of Applications



Peritumoral Treatment

- Film product
- Unidirectional delivery
- In the clinic for pancreatic cancer



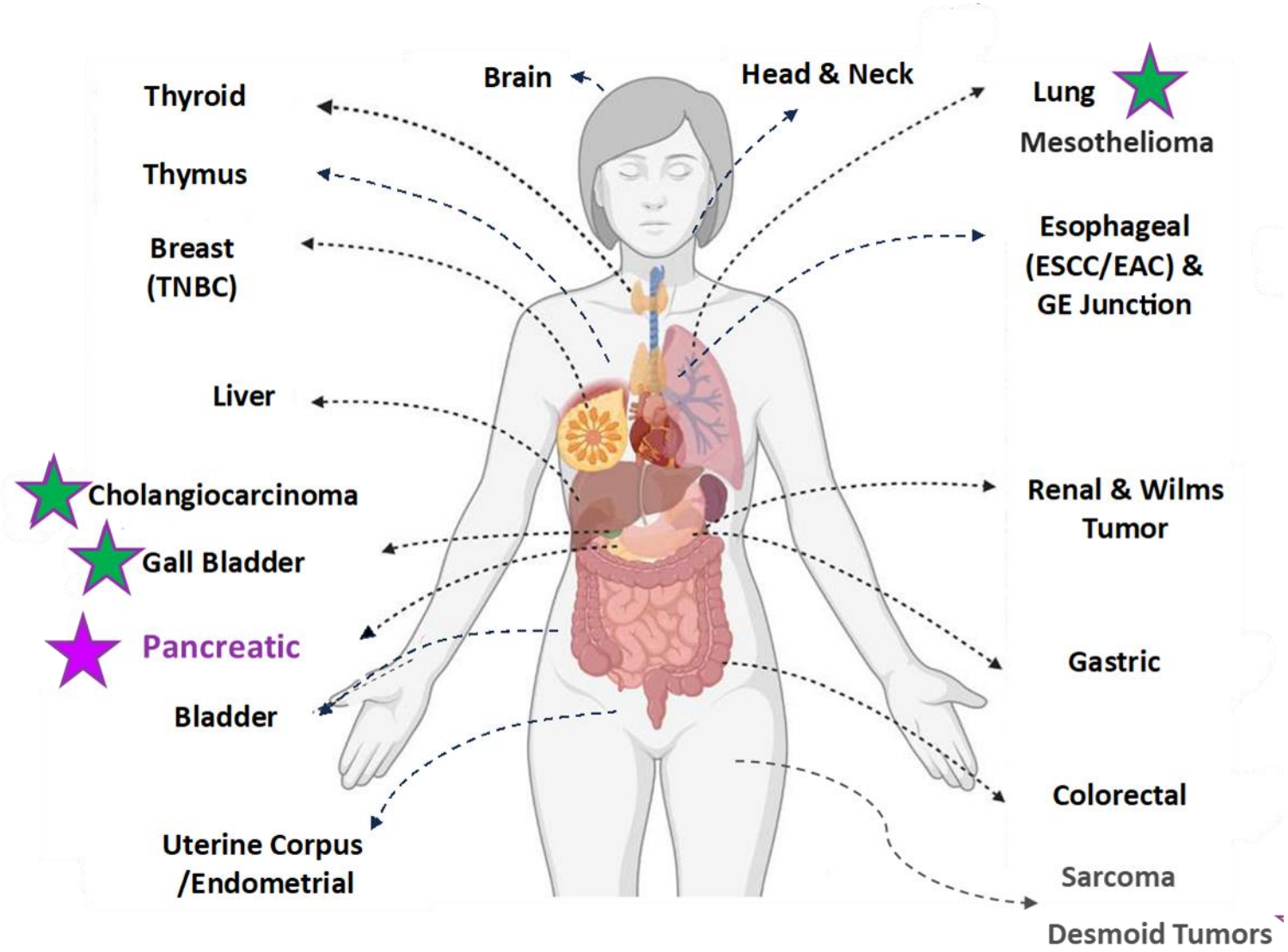
Intratumoral Treatment

- Plug product
- Omnidirectional delivery
- Scouting indications (e.g., lung cancer)

2-7

PANTHER

Pipeline Opportunity Assessment: Initial Set of Prioritized Indications



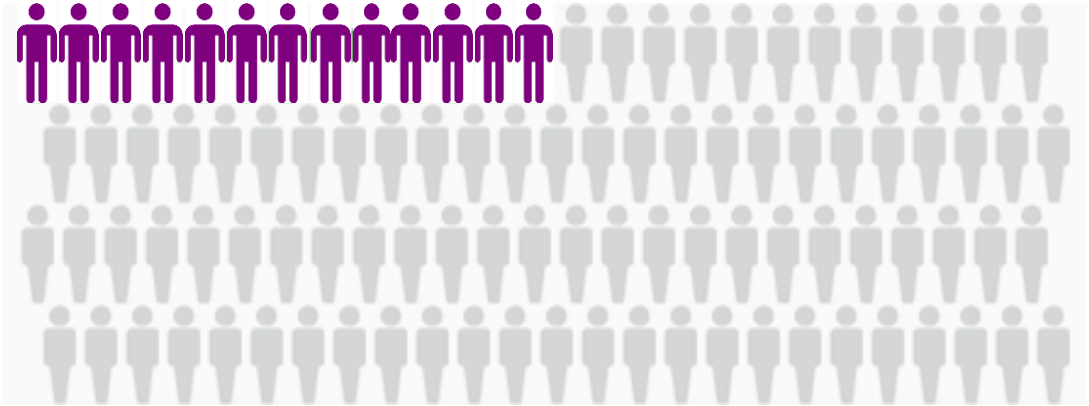
PTM-101: Treating Pancreatic Cancer

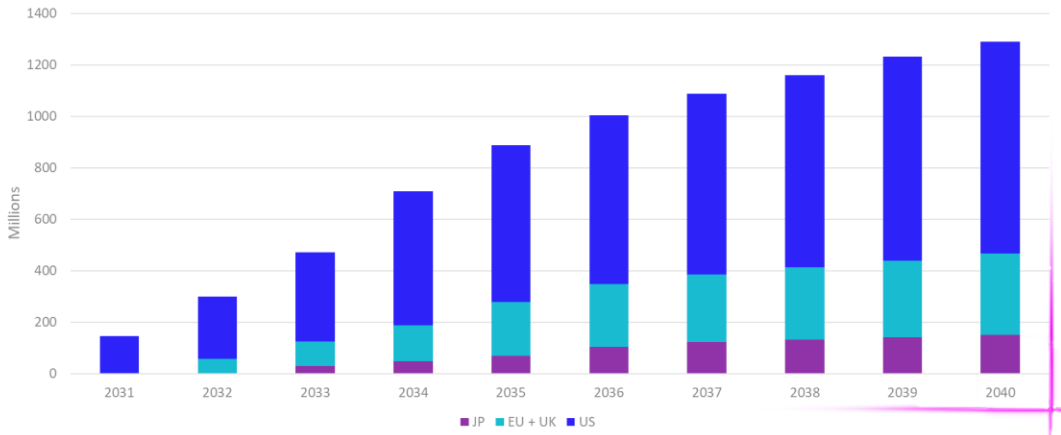
Pancreatic Cancer Assessment: Unmet Medical Need and Commercial Opportunity

Pancreatic cancer predicted to become 2nd leading cause of cancer death before 2030

13%

Survival Rate





PTM-101 1st Line Pancreatic Neoadjuvant Treatment Revenue Forecast: $1.3B in Peak Sales

PANTHER

Clinical Rationale for the Selection of Pancreatic Cancer as the Lead Indication for PTM-101

- **Surgical resection** for localized pancreatic cancer was found to increase median overall survival post surgery by 6 months (23 months mOS) and is considered "the only possibility of cure"[1]
- **Reduction in tumor volume** for localized pancreatic cancer has been shown to significantly increase overall survival by 7 months (22 months mOS) [2]

Key Factors Driving PanTher's Selection of Pancreatic Cancer as our First Program:

- Strong clinical rationale
- Easy access to tumor site using an established laparoscopic procedure
- Significant commercial opportunity (>$1B annual revenue)
- Excellent fit with PanTher's technology (see next slide)

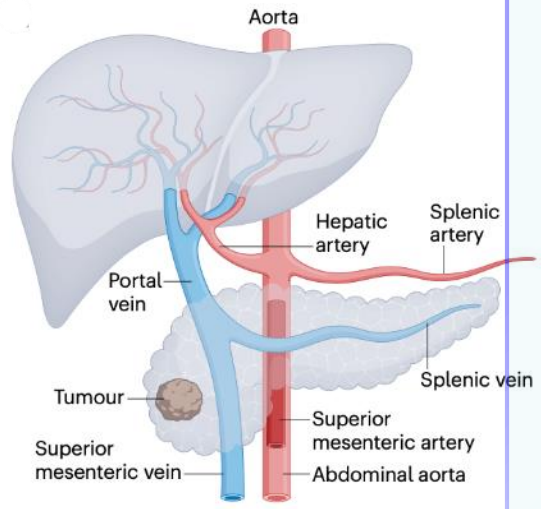
Sources:
[1] *BMC Surgery (2023) 23:296*
[2] *Journal of the National Comprehensive Cancer Network; Volume 20; Issue 8; August 2022*

PTM-101 Drug and Dosage Form:
Designed for Neoadjuvant Treatment of Pancreatic Cancer

2-12

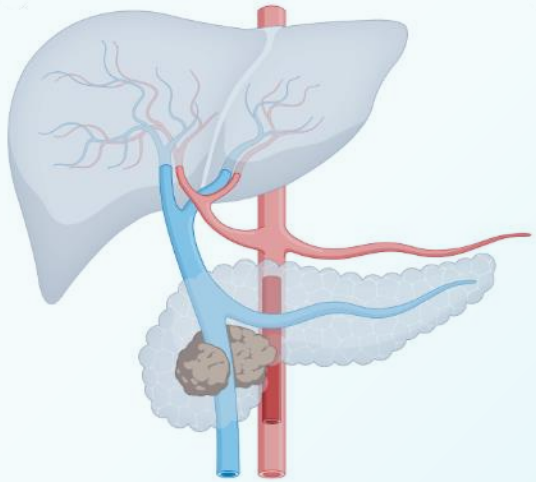
PTM-101 Clinical Study Target Patient Population: Staging of Pancreatic Cancer

Resectable



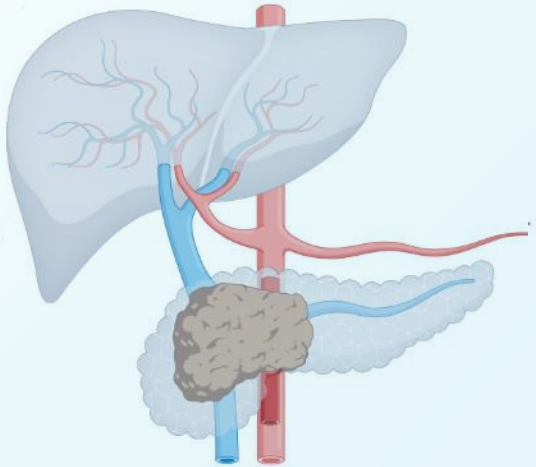
Non-malignant pancreatic tissue or fat separates the primary tumor from the superior mesenteric artery (SMA). An interface might exist between the tumor and the superior mesenteric vein (SMV), although the vein is not occluded.

Borderline Resectable



An interface exists between the primary tumor and SMA, over typically <50% of the vessel circumference. The superior mesenteric view might be occluded although must be technically reconstructable.

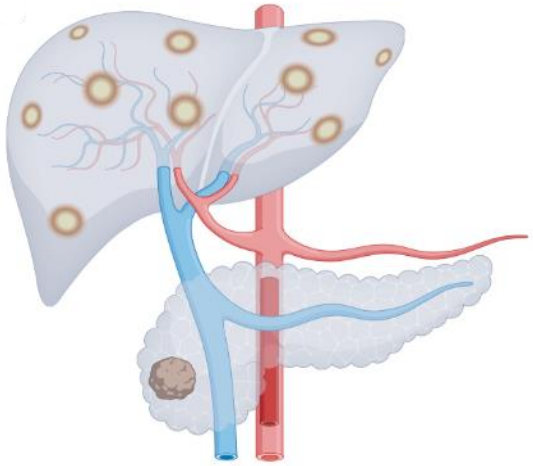
Locally Advanced



The primary tumor encases the SMA and/or is associated with an unreconstructable SMV.

PTM-101 Target Patient Population

Metastatic



Multiple metastases exists remote from primary tumor.

Adapted from: Nature Reviews Clinical Oncology, Volume 20, May 2023, 318–337

PANTHER

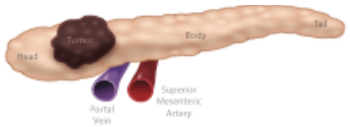
PTM-101 Target Patient Population: Patient Treatment Segmentation

Pancreatic Cancer Diagnoses
204,166 patients/year (US + EU)

Metastatic (50%)
102,083 patients/year

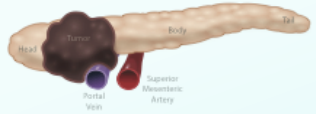
PTM-101 Lead Indication:1st Line Neoadjuvant Treatment
- Reduction in tumor volume
- Increase % of patients going to resection (and R0 rate)
- Significant improvement in PFS/OS

Resectable (15%)
30,625 patients/year



Neoadjuvant Chemo
(e.g., FOLFIRINOX)

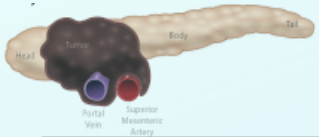
Borderline Resectable (15%)
30,625 patients/year



Neoadjuvant Chemo
(e.g., FOLFIRINOX)

PTM-101
Target Patient Population

Locally Advanced (20%)
40,833 patients/year



Neoadjuvant Chemo
(e.g., FOLFIRINOX)

Surgical Resection

Eligible for Resection

Assess for Surgery

Not Eligible for Resection

Unresectable

2-14

PANTHER

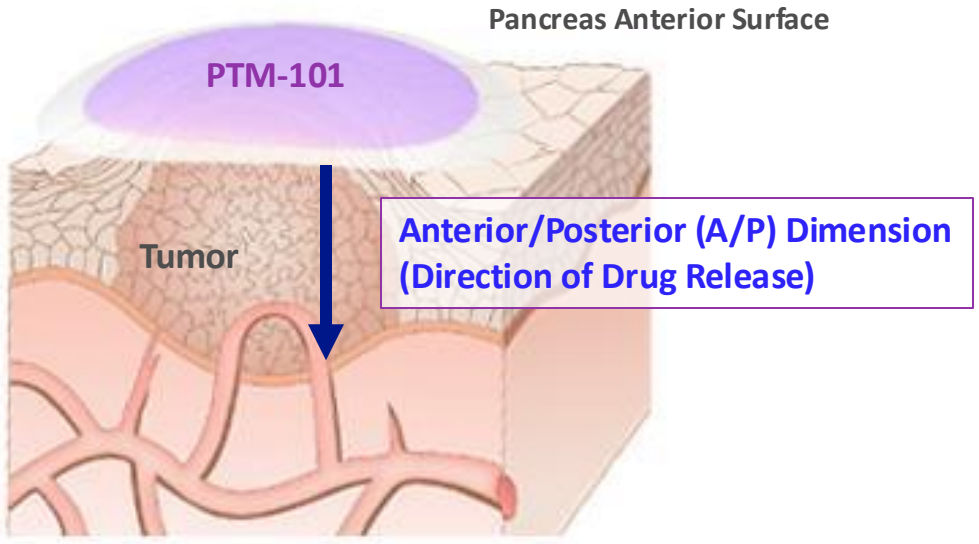
PTM-101 Phase 1 Clinical Trial: Early Encouraging Results with Lower-Dose Treatment

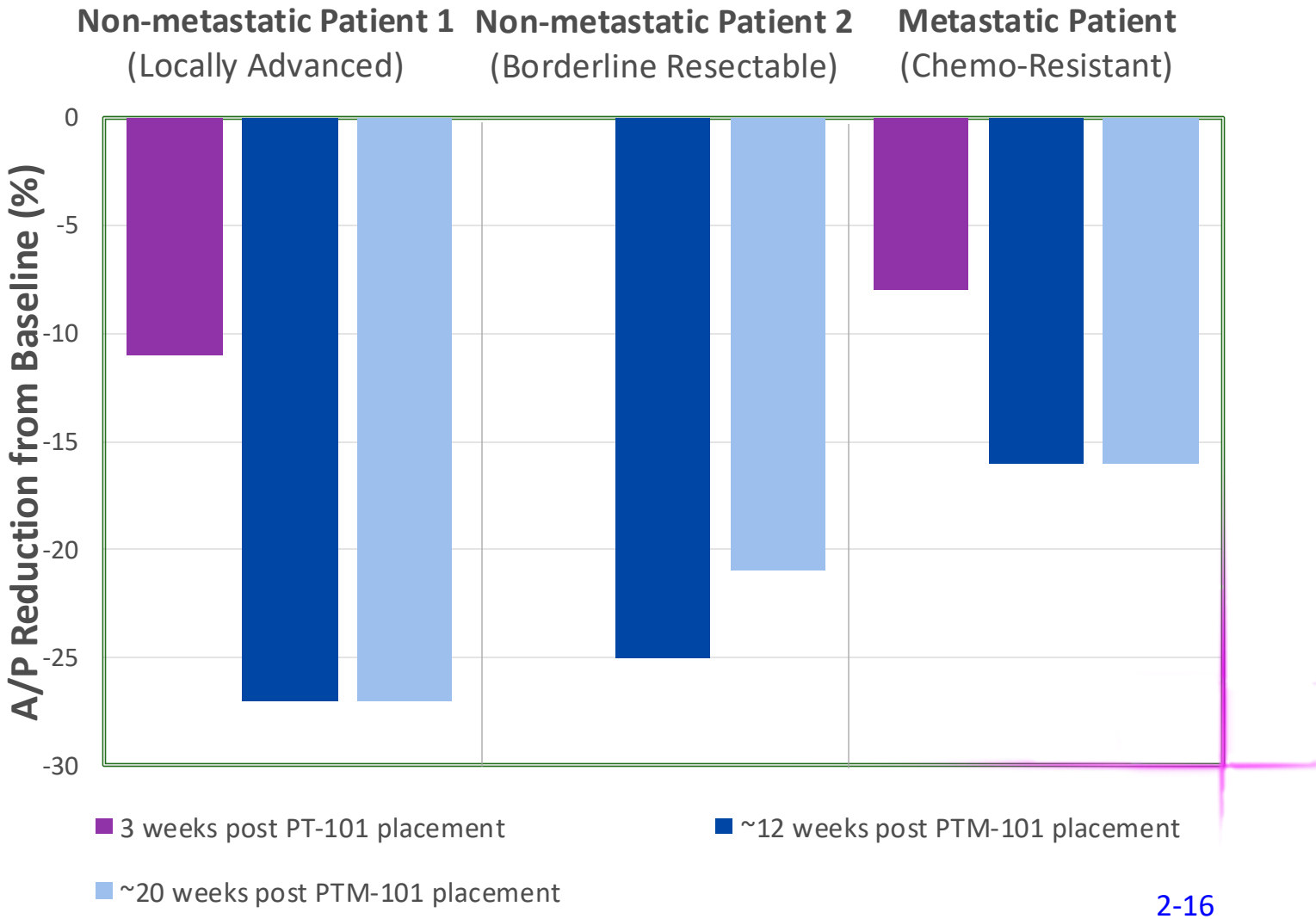
- ✓ **Excellent safety profile,** well tolerated in all patients with no SAEs, no peritonitis, pancreatitis, infection, or hematologic toxicity
- ✓ **No detectable** level of paclitaxel systemically at any tested timepoint
- ✓ **Minimal incremental operating room time** (<20 minutes) for successful placement of PTM-101
- ✓ **Anti-tumor response** demonstrated

2-15

PANTHER

PTM-101 Phase 1 Clinical Trial: Favorable Response in the Direction of Drug Release



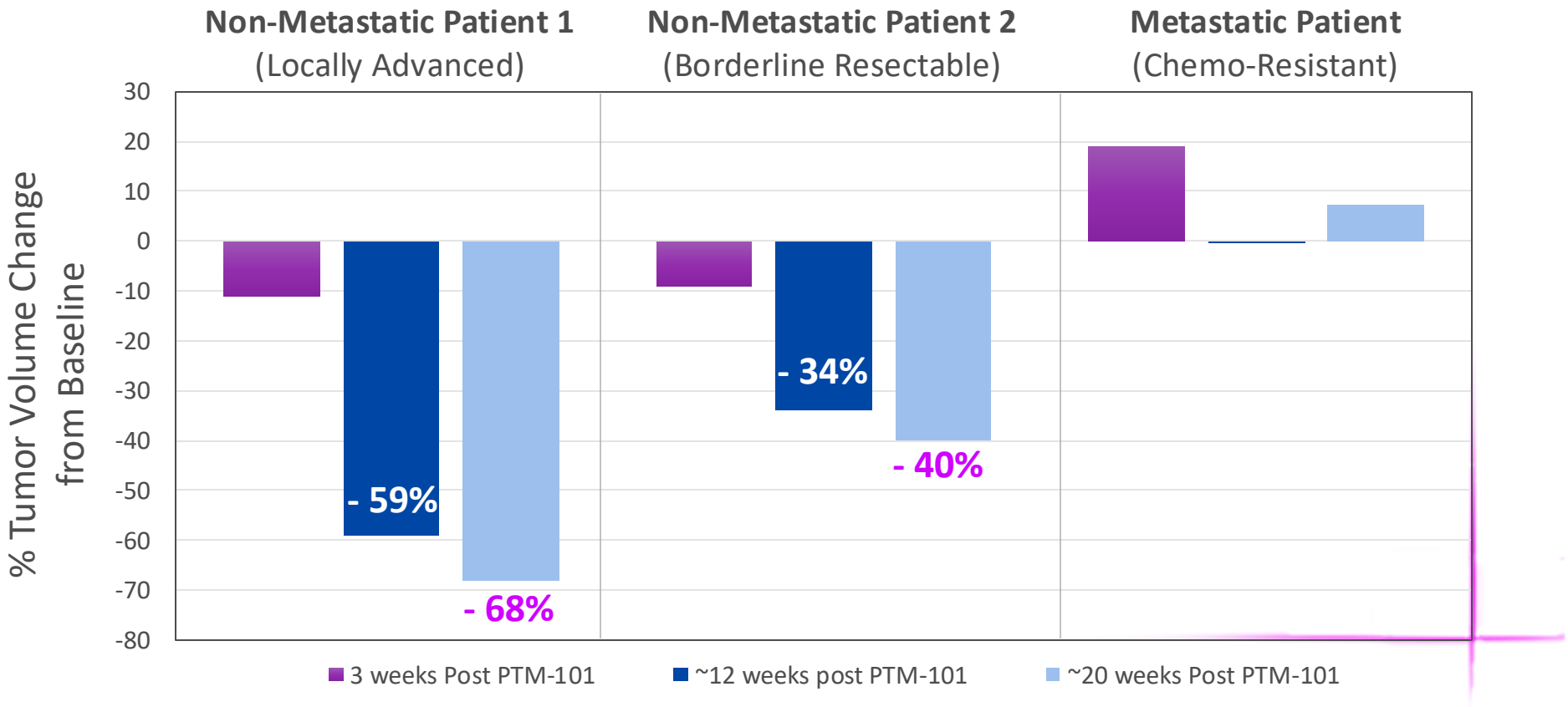


2-16

PANTHER

PTM-101 Phase 1 Clinical Trial: Substantial Reduction in Tumor Volume at our Lowest Dose

Two out of three patients had substantial overall tumor volume reduction, with limited tumor volume growth in a patient with more advanced disease



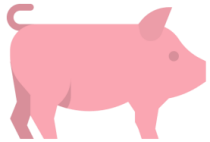
Reported median volumetric reduction after ~12 weeks of SOC neoadjuvant treatment[1]: **21%**

2-17

[1] *JNCCN; Volume 20; Issue 8; August 2022*

PANTHER

PTM-101 Progress Overview since CPRIT Award



2023

Opened Texas Lab

Opened Austin TX based laboratory supporting process development.

Product GMP mfg

690 products manufactured. Ready for shipment to clinics.

Animal Studies

IND enabling study with positive release and toxicity results.

IND Accepted

Submission July 2024; study may proceed letter August 2024.

Clinical Site Setup

5 sites selected including MD Anderson. 3 sites expected to enroll by March.

Designs for Texas MFG

Designed 5000 sq ft MFG site in Austin TX. Scaling for Phase 2/3 & commercial production.

TODAY

2-18

PANTHER

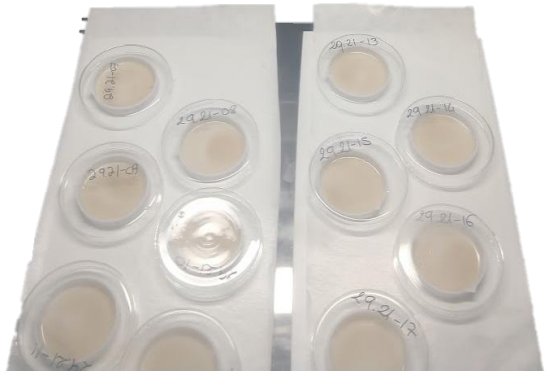
Austin Operations

- Office opened May ‘23
- Laboratory opened Oct ‘24
- Lamination process development & materials characterization

Evolution of Manufacturing Methods

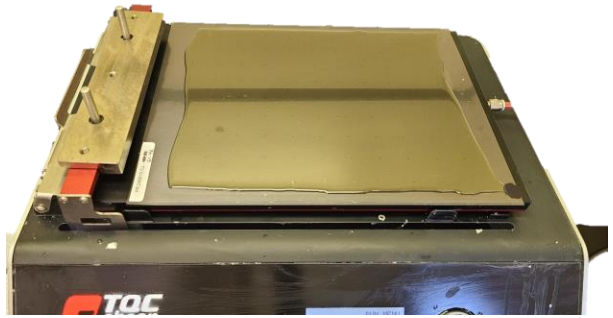
2021

Fist-in-human study → **Phase 1b Study** → **Future Manufacturing**



Single Product

- Highly manual
- 20 product lots



Sheet of Products

- Still manual
- Sheets enable parallel processing
- 120 product lots

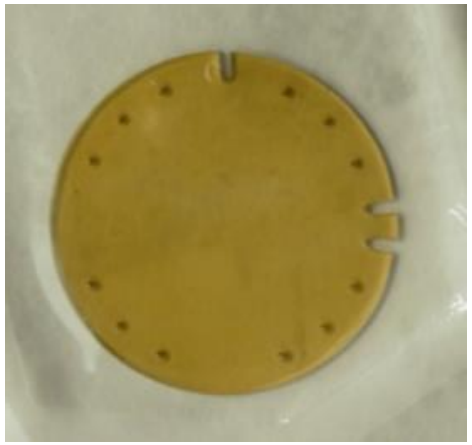
Roll of Products

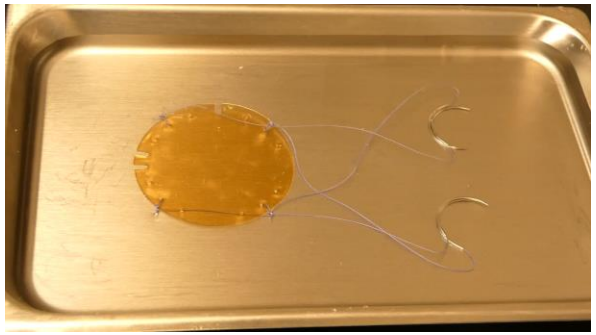
- Automated processing
- Roll-to-roll configuration
- 500 product lots

2-20

Completed GMP Manufacturing Campaign

- 5 clinical lots
- 2 doses (200mg and 400mg)
- In total 690 products were manufactured





2-21

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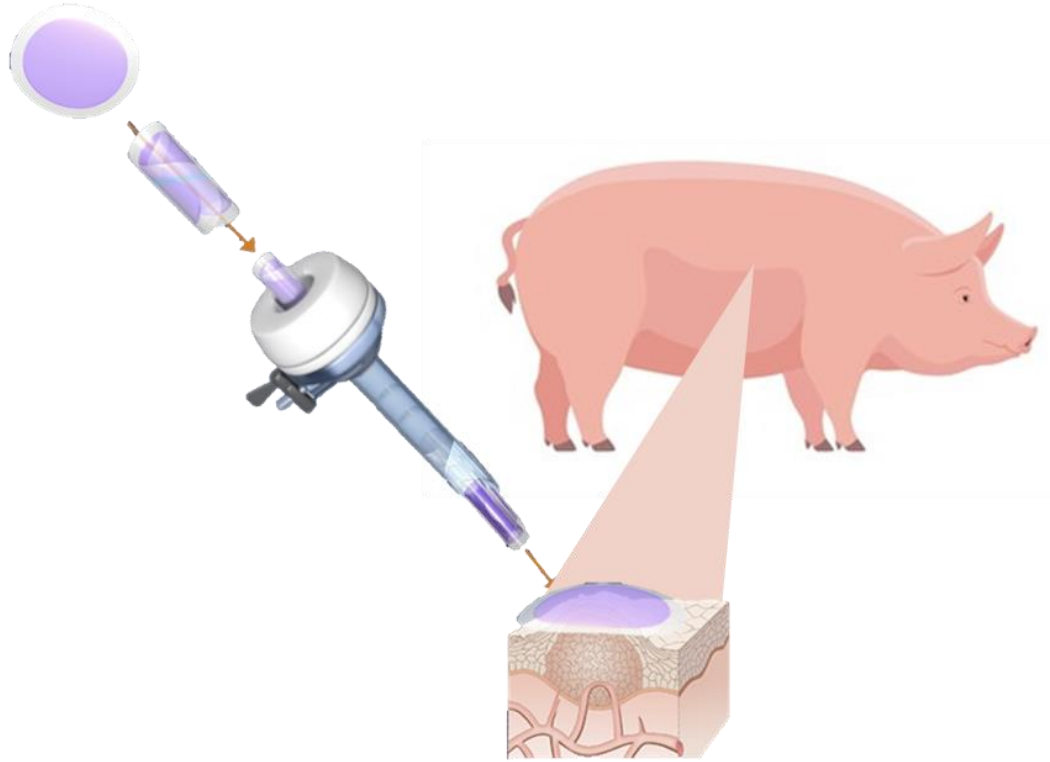
Clinical Products Ready for Distribution

- Products stored at 3rd party logistics partner for on demand shipping to clinics

IND-Enabling GLP Tox and PK Animal Studies

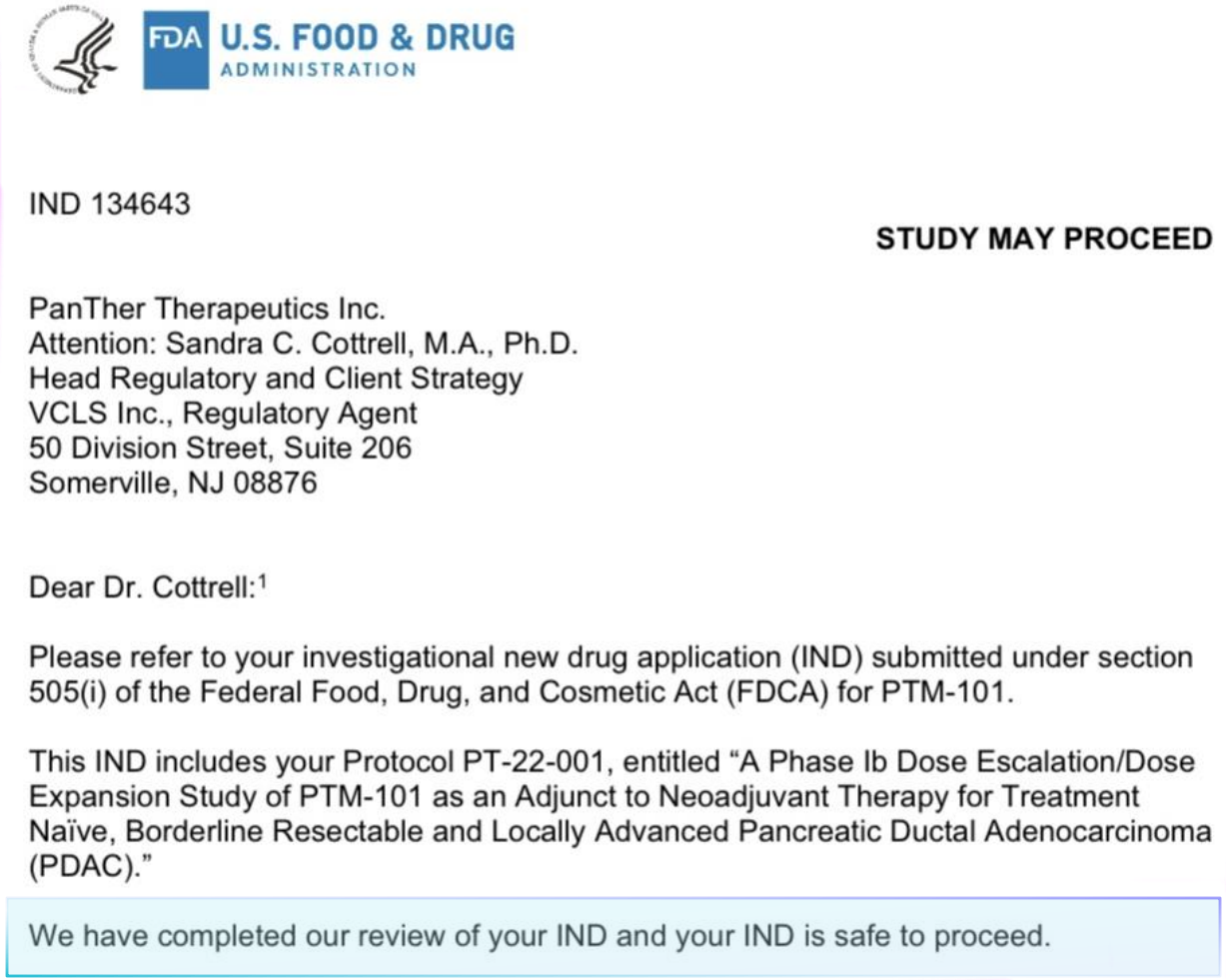
- Completed animal studies in 36 pigs
  - Lowest Dose (1x)
  - Higher Dose (4x)
  - Exaggerated Dose (12x)
- Studies assessed
  - systemic drug toxicity and drug release
- Successfully validated hypothesis:
  - Expected drug release and local retention
  - Showed no systemic drug exposure and toxicity
- Positive results enabled IND submission



2-23

IND Submitted and Cleared

- Clinical study documents approved
  - PT-22-001 Protocol
  - PT-22-001 Informed Consent Form
  - PTM-101 Investigator Brochure
  - PTM-101 Instructions for Use
- Clinical trial WCG Central IRB approved
  - Documents sent to Sites
- Partnered with clinical vendors to support clinical trial
  - Perspective (central imaging)
  - IQVIA (central lab and PK analysis)
  - Catalyst (clinical research organization)



FDA U.S. FOOD & DRUG ADMINISTRATION

IND 134643

STUDY MAY PROCEED

PanTher Therapeutics Inc.
Attention: Sandra C. Cottrell, M.A., Ph.D.
Head Regulatory and Client Strategy
VCLS Inc., Regulatory Agent
50 Division Street, Suite 206
Somerville, NJ 08876

Dear Dr. Cottrell:[1]

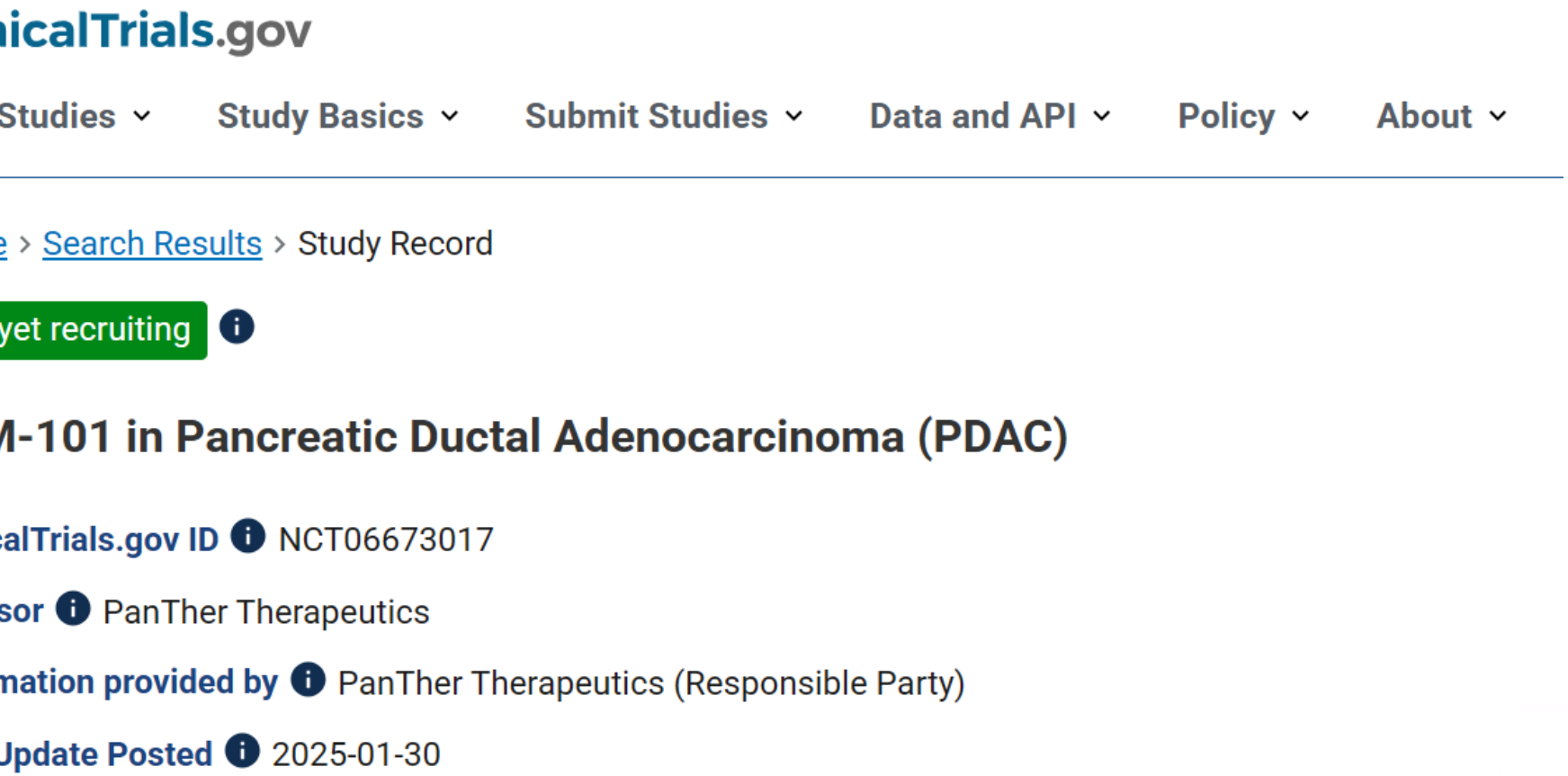
Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PTM-101.

This IND includes your Protocol PT-22-001, entitled "A Phase Ib Dose Escalation/Dose Expansion Study of PTM-101 as an Adjunct to Neoadjuvant Therapy for Treatment Naïve, Borderline Resectable and Locally Advanced Pancreatic Ductal Adenocarcinoma (PDAC)."

We have completed our review of your IND and your IND is safe to proceed.

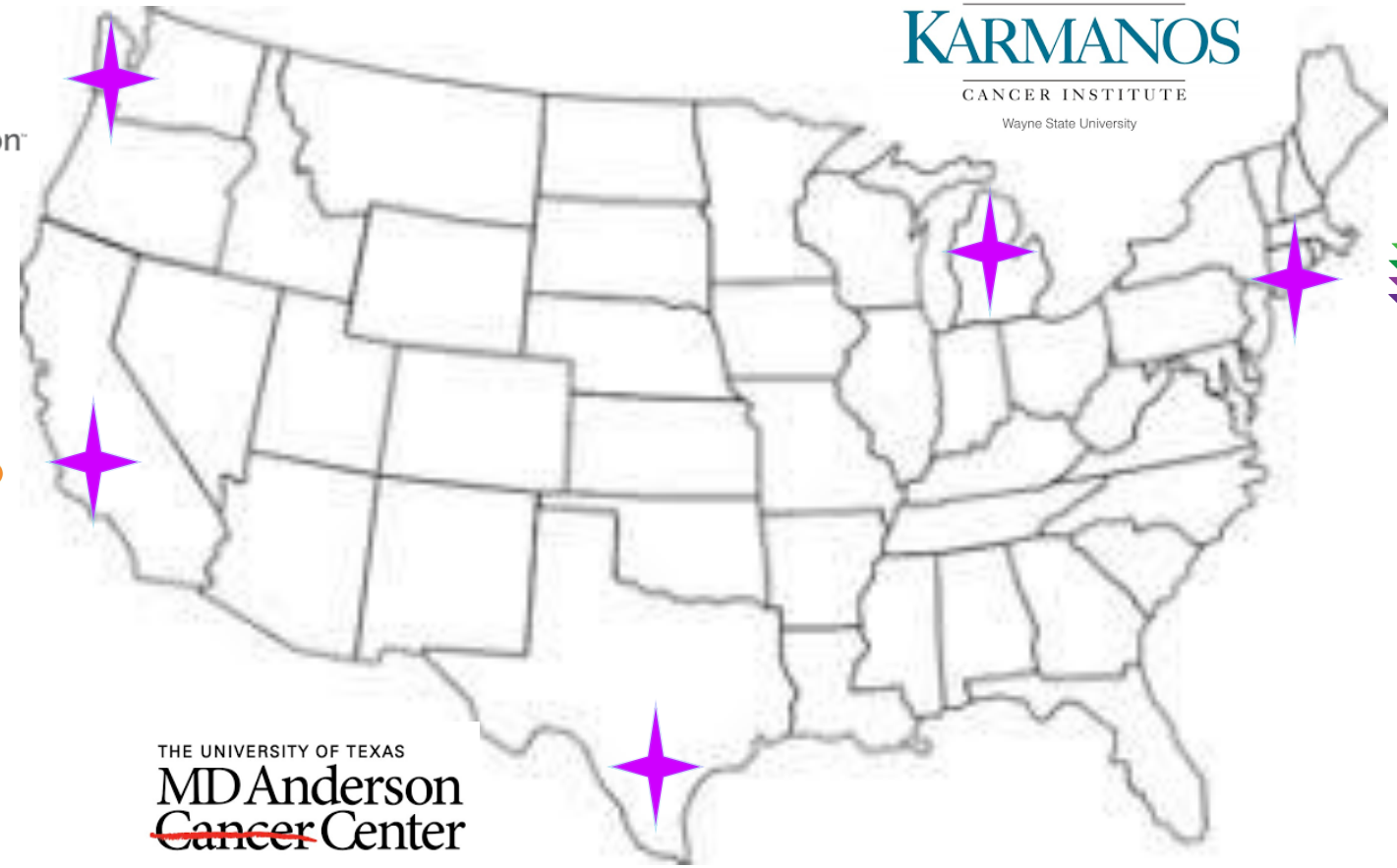
Clinical Trial Registered

- Posted on the ClinicalTrials.gov public website in November 2024 (NCT06673017)



Ready to Dose First Patient

5 sites selected with study start-up process ongoing



Virginia Mason

BARBARA ANN KARMANOS CANCER INSTITUTE
Wayne State University

Northwell Health Cancer Institute

hoag.

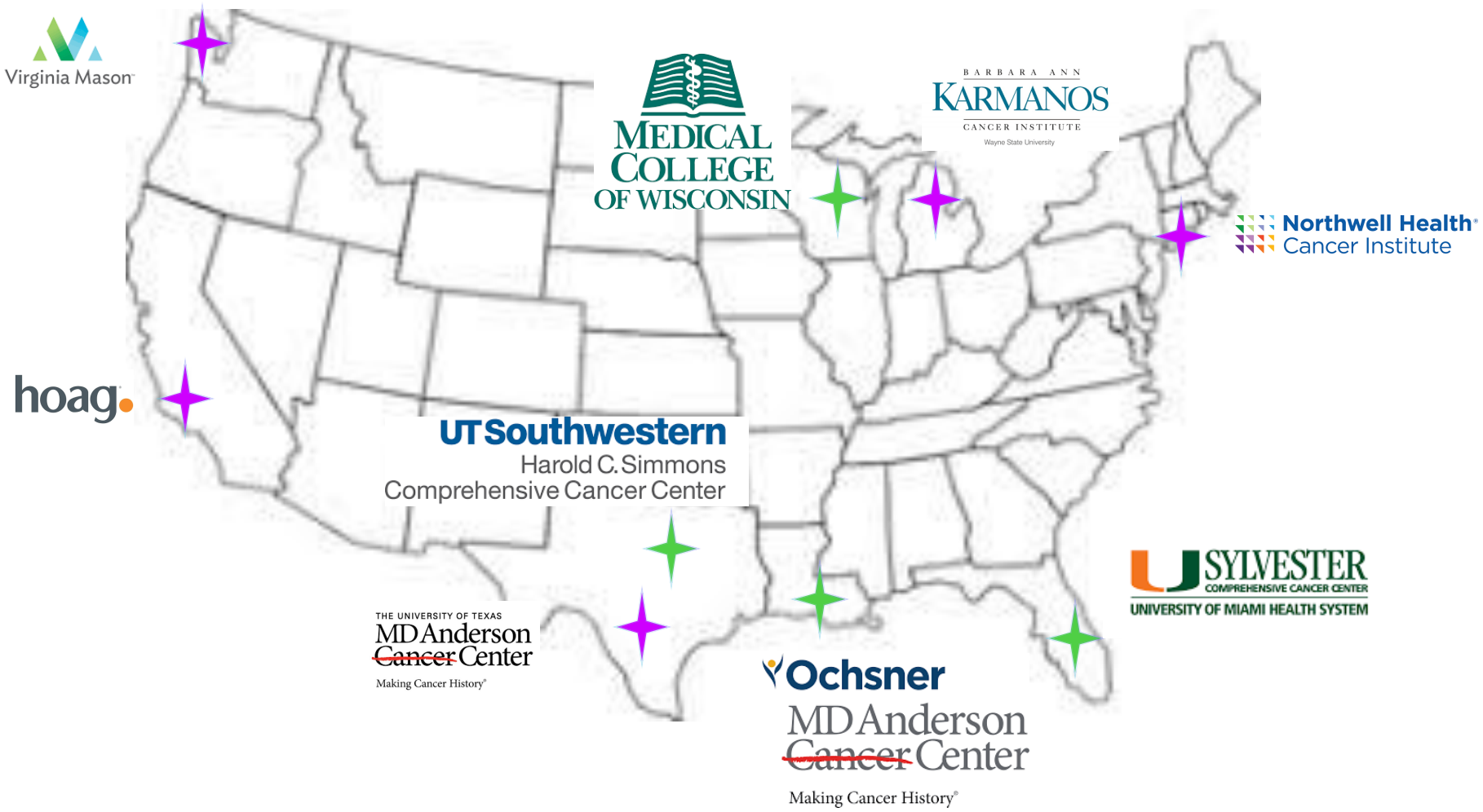
THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History®

3 sites expected to open to enrollment in March

PANTHER

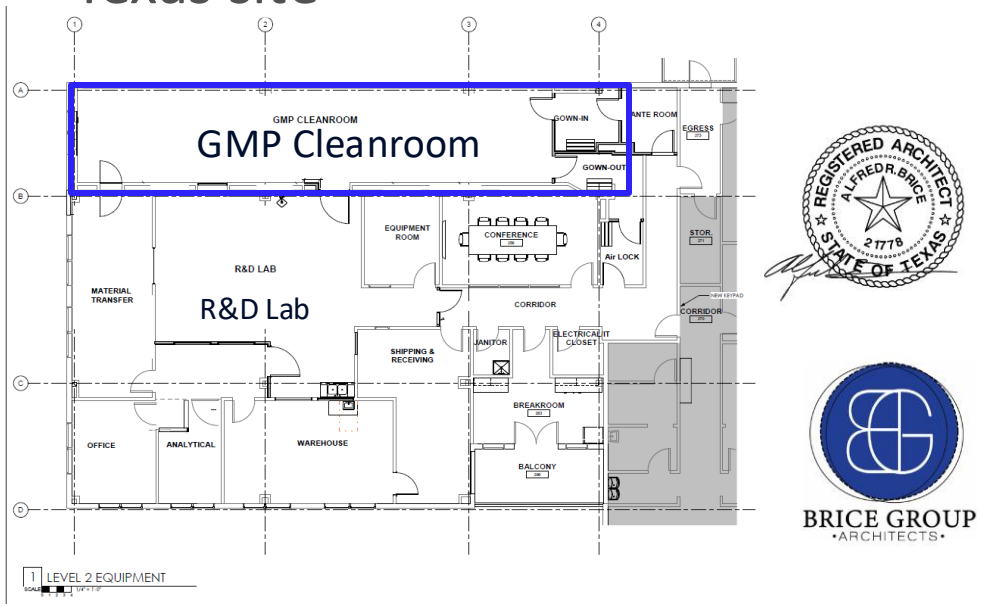
Progress Toward Expansion of Clinical Sites

Selection of additional sites for dose expansion ongoing



Planning for the Future – Buildout of Texas Clinical Manufacturing Facility (CMF)

- Designs complete for Austin, TX, 5000 sq ft manufacturing site includes upgrade of existing cleanroom
- Scaling for pivotal trials & commercial production at Austin Texas site



REGISTERED ARCHITECT
ALFRED R. BRICE
21778
STATE OF TEXAS

BRICE GROUP
•ARCHITECTS•

PANTHER

It Takes a Village to Bring the Fight against Cancer Directly to the Target

It Takes a Village to Bring the Fight against Cancer Directly to the Target…. And to Times Square

PANTHER THERAPEUTICS

A QUANTUM LEAP FORWARD
in the fight against cancer

CPRIT Oversight Committee

February 19, 2025

Laura Indolfi, CEO – lindolfi@panthertx.com

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	CHIEF EXECUTIVE OFFICER REPORT
DATE:	FEBRUARY 11, 2025

The Chief Executive Officer Report presented at the February 19 Oversight Committee meeting will include a brief update on grant funds available, personnel, the CPRIT 2024 Annual Report, and the 89th Texas Legislative session. I may add other items as warranted. For your reference, I have included copies of the November/December 2024 and January 2025 CPRIT Activities Updates behind this memo.

FY 2025 Grant Awards Funds Available and CPRIT Dashboard

As shown in the attached "FY 2025 Grant Funds Available" document, if the Oversight Committee approves the Academic Research awards at the Program Integration Committee's recommended level of $67.75 million, we will have $116 million remaining for grant awards in FY 2025.

I have also attached CPRIT's dashboard of metrics that we track on a regular basis.

Personnel

CPRIT has filled 53 full-time equivalent (FTE) positions, including 9 long-term contract employees. This amount exceeds CPRIT's authorized FTE count of 44 positions.

CPRIT's 2024 Annual Report

As required by law, CPRIT submitted our annual report for fiscal year 2024 to the governor and the Texas legislature on January 31. The report, which CPRIT makes available exclusively online at http://annualreport.cprit.texas.gov highlights the progress CPRIT and our grantees have made in FY 2024 towards the agency's three-part mission to invest in the cancer research prowess of Texas' academic institutions, to create and grow the state's life science infrastructure, and to identify and fund innovation in the prevention, identification, treatment, and cures for cancer.

CPRIT's statute specifies several required components for the annual report, including:

- the grants approved during the fiscal year

- a summary of research findings reported in the fiscal year
- an assessment of CPRIT's grants and the overall strategy of the research program
- an economic estimate of how much cancer has cost the state
- the agency's compliance activities
- information related to reviewers' conflicts of interest

In addition to these required elements, we incorporate numerous grantee highlights and program features that illustrate the connection between the CPRIT grant projects and the advancements made in Texas' fight against cancer. In this year's report, we emphasized our grantees' work in cancer clinical trials, an essential component of CPRIT's mission.

While the report is a team effort across the entire agency, CPRIT's Communications Director Mark Loeffler, Digital Communications Specialist Justin Rand, technical writer Bridget Barstow, Information Resource Manager Shannon Cusick, and IT designer Royce Hart deserve special credit for the enormous amount of work necessary to put together the 2024 report.

Legislative Update

The 89th Legislative Session convened in regular session at noon on January 14 and will adjourn *sine die* at midnight on June 2. The Texas Senate has three new members, and the Texas House has 31 new members.

Both chambers filed their draft budget bills, Senate Bill 1 (SB1) and House Bill 1 (HB1) on January 22. Both bills provide CPRIT's full, constitutionally authorized annual appropriation of $300 million. In addition, both include CPRIT's requested additional 10 FTEs and remove the appropriations rider that transferred $3+ million per year to the Cancer Registry at the Texas Department of State Health Services. As a result, CPRIT has a single exceptional item request – increasing the Chief Executive Officer and Chief Scientific Officer exempt salaries by 10%.

The Senate Committee on Finance held CPRIT's budget hearing January 29. Vice Presiding Officer Cindy Payne and I presented our budget request. The committee had questions regarding CPRIT's return on investment, research accomplishments, revenue sharing, and the allocation of CPRIT's award portfolio to prevention grants. Several advocates testified in support of CPRIT at the hearing. We will follow up with the committee regarding requested items.

As of February 10, Speaker Dustin Burrows has not yet named House Committees. We have received preliminary guidance to expect to testify before the House Appropriations Committee the week of February 24, likely February 24 or 25.

Legislators have filed 2,837 bills in the House and 1,324 bills in the Senate, for a total of 4,161 bills as of February 10. Legislators will continue to submit bills through the March 14 bill-filing deadline.

It appears that legislators have not filed any bills as of February 10 that directly affect CPRIT or CPRIT's enabling statute, Texas Health & Safety Code Chapter 102.

Since the November Oversight Committee meeting, Deputy Executive and Chief Operating Officer Heidi McConnell and I have met with Texas state senators and members of their staff, including Sen. Pete Flores, Sen. Sarah Eckhardt, and staff for Sen. Carol Alvarado. We will continue to schedule meetings with state senators, state representatives, and their staff to update members on our activities.

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CPRIT has awarded **2,038** grants totaling **$3.74 billion:**

- 311 prevention awards totaling $394.2 million
- 1,727 academic research and product development research awards totaling $3.35 billion

Of the $3.35 billion in academic research and product development research awards,

- 33.6% of the funding ($1.12 billion) supports clinical research projects.
- 22.8% of the funding ($762.1 million) supports translational research projects.
- 29.0% of the funding ($971.4 million) supports recruitment awards.
- 11.9% of the funding ($397.2 million) supports discovery stage research projects.
- 2.7% of the funding ($91.6 million) supports training programs.

CPRIT has 9 open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 6 Academic Research

FY 2025 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 27,286,961	$ 251,369,432		$ 21,343,607	$ 300,000,000
Approved Adjustment to Operating Costs		(1,990,411)		1,990,411	
Appropriations Transfer to DSHS		(3,118,032)		3,118,032	
Adjusted Appropriations	$ 27,286,961	$ 246,260,989		$ 26,452,050	$ 300,000,000
Total Available for All Grants			$ 273,547,950		
1% of Total Available Grant Funding			2,735,480		
Adjusted Grant Award Funding	$ 27,286,961	$ 243,525,510			$ 270,812,471

	Prevention Grants	Academic Research Grants	PD Research Grants			
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 27,286,961	$ 172,382,692	$ 73,878,297			$ 273,547,950
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 27,286,961	$ 170,467,857	$ 73,057,653			$ 270,812,471
Announced Grant Awards						
11/20/24 Prevention Grant Awards (8)	$ 13,446,501	$ -	$ -			
11/20/24 ACR Recruitment Awards (5)	-	12,000,000	-			
11/20/24 PDR Company Grant Awards (9)	-	-	63,566,376			
Announced Grant Award Subtotal	$ 13,446,501	$ 12,000,000	$ 63,566,376	$ -		$ 89,012,877
Grant Award Adjustments						
1/3/25 Declined Recruitment (UTMDACC - Goto)	$ -	$ (2,000,000)	$ -			$ (2,000,000)
Revised Grant Award Subtotal	$ 13,446,501	$ 10,000,000	$ 63,566,376			$ 87,012,877
Available Funds as of January 3, 2025	$ 13,840,460	$ 160,467,857	$ 9,491,277			$ 183,799,594
Pending Grants-PIC Recommendations						
ACR Recruitment Awards (6)	$ -	$ 16,000,000	$ -			
ACR IIR Awards (Multi-Category, 45)	-	45,753,637	-			
ACR CAP Awards (1)	-	3,000,000	-			
ACR CFSA Award (1)	-	2,999,989	-			
Pending Award Subtotal	$ -	$ 67,753,626	$ -			$ 67,753,626
Total Potential Grant Funding Committed	$ 13,446,501	$ 77,753,626	$ 63,566,376			$ 154,766,503
Available Funds as of February 20, 2025	$ 13,840,460	$ 92,714,231	$ 9,491,277			$ 116,045,968
1% Grant Funding Buffer	$ -	$ 1,914,836	$ 820,644			$ 2,735,480
Total Remaining Funds	$ 13,840,460	$ 94,629,066	$ 10,311,921			$ 118,781,447

Operating Budget Detail	
Indirect Administration	$ 4,910,893
Grant Review & Award Operations	16,058,895
Adjustment to Grant Review & Award Operations	1,990,411
Salary Adjustment	373,819
Subtotal, CPRIT Operating Costs	$ 23,334,018
Cancer Registry Operating Cost Transfer	3,118,032
Total, Operating Costs	$ 26,452,050

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2025

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			22										22	
New Grant Contracts Signed	7	18	6	6	11								48	
New Grant Contracts In Negotiation			17										17	
Grant Reimbursements Processed (#)	229	287	250	241	261								1268	
Grant Reimbursements Processed ($)	$ 24,564,272	$ 24,275,097	$ 12,108,275	$ 17,252,369	$ 31,061,183								$ 109,261,196	
Revenue Sharing Payments Received	$ 8,333	$ 1,168	$ 217,853	$ 4,513	$ 254,499								$ 486,365	$ 10,977,409
Grants Awarded (#)/ Applications Rec'd (#)	19%	19%	19%	19%	19%									
Grantee Compliance Trainings	1	4	0	0	1								6	
Grantee Compliance Monitoring Visits	0	1	4	2	3								10	
Awards with Delinquent Reimbursement Submission (FSR)			0											
Awards with Delinquent Matching Funds Verification			2											
Awards with Delinquent Progress Report Submission			0											
MISSION														
Open RFAs	12	12	12	12	3									
Prevention Applications Received	0	0	0	21	0								21	1,062
Product Development Preliminary Applications Received	0	0	0	0	0								0	293
Product Development Full Applications Received	0	0	0	0	0								0	712
Academic Research Applications Received	0	7	5	160	5								177	9,635
Help Desk Calls/Emails	87	103	128	149	148								615	
Number of Research Grants Announced (Annual)	0		5										5	
Recruited Scientists Contracted														322
Number of Product Development Grants Announced (Annual)	0		9										9	
Life Science Companies Recruited (in TX)														17
Number of Product Development Jobs Created & Maintained														1,866
Number of Prevention Grants Announced (Annual)			8										8	
Total Number of Education, Navigation and Training Services			171,310										171,310	
Total Number of Clinical Services			62,321										62,321	
Published Articles on CPRIT-Funded Projects (#)														
Clinical Studies (#)														273
Number of Patent Applications														
Number of Patents Resulting from Research														
TRANSPARENCY														
Total Website Hits (Sessions)	19,750	11,061	11,792	8,744	13,759									
Total Unique Visitors to Website (Users)	15,061	7,456	7,646	5,859	9,482									

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR NOVEMBER/DECEMBER 2024
DATE:	DECEMBER 31, 2024

Topics in this memo address CPRIT activities in November and December, including recent milestones in our fight against cancer, a staffing update, outreach and legislative efforts, upcoming CPRIT-related events that may be of interest to Oversight Committee members, and updates from Compliance, Programs, and Operations.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- The Basser Center for BRCA at the Abramson Cancer Center of the University of Pennsylvania announced on October 21 that CPRIT Scholar Patrick Sung, D.Phil., director of the Greehey Children's Cancer Research Institute, associate dean for research, and professor of biochemistry and structural biology, Joe R. and Teresa Lozano Long School of Medicine at The University of Texas Health Science Center at San Antonio, received the 2024 Basser Global Prize.

  The Basser Global Prize recognizes a leading scientist who has advanced BRCA1 and BRCA2-related research. Individuals with mutations in the BRCA1 and BRCA2 genes are at an increased risk of breast, ovarian, pancreatic, and prostate cancers. The normal function of BRCA1 and BRCA2 genes involves repairing damage to DNA. When these genes mutate DNA damage builds up within cells, greatly increasing the risk of cancer. Dr. Sung's research on a specific genome repair pathway known as homology-directed repair has led to foundational discoveries regarding the mechanisms of DNA damage repair by providing a detailed picture of how BRCA genes work at a molecular level and revealing potential new targets for cancer therapy.

  UT Health San Antonio recruited Dr. Sung from Yale University in 2018 with a $6 million CPRIT Recruitment of Established Investigators grant (RR180029).

- The V Foundation for Cancer Research named CPRIT Scholar Elizabeth Wasmuth, Ph.D., this year's V Foundation Abeloff Scholar on November 20, in recognition of her grant proposal receiving the highest score. Dr. Wasmuth is an assistant professor in the Department of Biochemistry and Structural Biology, Mays Cancer Center at The University of Texas Health Science Center at San Antonio, and the co-founder and co-director of the institution's

Cryogenic-EM Facility. This award from the V Foundation for Cancer Research, founded by ESPN and renowned basketball coach Jim Valvano, will provide support for Dr. Wasmuth's proposal related to targeting the altered function of steroid hormone receptors in cancers such as prostate, breast, uterine, and ovarian cancer. UT Health San Antonio recruited Dr. Wasmuth from Memorial Sloan Kettering Cancer Center and the Rockefeller University with the support of a $2 million CPRIT First-Time, Tenure-Track Faculty Members grant (RR220068) in 2022.

- On November 20, Becton, Dickinson and Company, one of the largest global medical technology companies in the world, reported the launch of a Human Papillomavirus (HPV) self-collection screening pilot program at Su Clinica, a Federally Qualified Health Center (FQHC) with locations in Brownsville, Harlingen, Raymondville, and Santa Rosa. CPRIT-funded researchers from The University of Texas MD Anderson Cancer Center are working with the FQHC to improve cervical cancer screening in underserved communities in Texas.

  The MD Anderson project team, led by Jane Montealegre, Ph.D., Department of Behavioral Science, Division of Cancer Prevention and Population Sciences, and Kathleen Schmeler, M.D., professor in the Department of Gynecologic Oncology and Reproductive Medicine, will work with Su Clinica to conduct the pilot study. The program at Su Clinica, supported by a $2.5 million CPRIT Prevention grant to MD Anderson and Dr. Montealegre (PP240017), will evaluate the implementation and effectiveness of self-collected HPV testing in a health care setting using Onclarity™, the Beckton, Dickinson's HPV Assay.

- The Swiss Chemical Society (SCS) announced on November 27 that CPRIT Scholar Julian West, Ph.D., of Rice University is the recipient of the Grammaticakis-Neumann Prize. This prize is a biennial global honor that recognizes a young scientist for groundbreaking achievements in experimental or theoretical photochemistry. Dr. West, an assistant professor and the Norman Hackerman-Welch Young Investigator in the Department of Chemistry, is a synthetic chemist whose laboratory designs novel chemical reactions.

  The SCS recognized Dr. West for his research in harnessing free radical intermediates through inner sphere photocatalysis – the acceleration of a reaction in the presence of a photocatalyst typically activated by light or irradiation - enabling innovative reactions previously considered unattainable. His work has significant implications for advancing organic synthesis and creating tools that develop next-generation therapeutics and materials. Rice recruited Dr. West in 2019 from the California Institute of Technology with a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR190025).

- The International Bancshares Corporation (IBC) Foundation awarded CPRIT grantee Patricia Chalela, Dr.P.H., the IBC Foundation Endowed Professorship in Health Promotion Research on December 3. The IBC Foundation is a private foundation dedicated to supporting charities that enrich the community and improve the health and wellness of people in Texas and Oklahoma. The foundation made a $2 million donation that established four endowed professorships at The University of Texas Health Science Center at San Antonio.

Dr. Chalela, associate professor, Department of Population Health Sciences in the Institute for Health Promotion Research at UT Health San Antonio, is co-program director of *Quitxt*, a CPRIT-funded bilingual text program that provides interactive messages through texts or WhatsApp chat with visual and video content employing theory- and evidence-based techniques to prompt and sustain smoking cessation. CPRIT awarded a $2 million Individual Investigator Research Award for Prevention and Early Detection (RP230117) in 2023 to UT Health San Antonio and Dr. Chalela to evaluate the effectiveness of the *Quitxt* mobile cessation intervention. Her study contributes to public health by evaluating the effectiveness of this scalable, evidence-based intervention designed to help young adults stop smoking.

UT Health San Antonio and Amelie Ramirez, Dr.P.H., M.P.H., launched *Quitxt* in 2015 with a $1.4 million CPRIT Prevention (PP140176) grant. Since 2015, CPRIT has awarded two additional Prevention grants to support the *Quitxt* program (PP170099, PP180092).

- On December 10, the National Academy of Inventors announced the election of its 2024 class of fellows, recognizing innovators who are advancing novel areas of research and "making significant tangible societal and economic impacts" in science and consumer technologies. Those named as 2024 fellows include six CPRIT grantees:

  CPRIT Scholar Omid Veiseh, Ph.D., is a professor of bioengineering and faculty director of the Rice Biotech Launch Pad, a Houston-based accelerator focused on expediting the translation of the university's health and medical technology discoveries into cures. He also serves as managing partner for RBL LLC, a Houston-based company incubator launched this year that evolved from the Rice Biotech Launch Pad. Dr. Veiseh is developing next-generation treatments by combining synthetic biology, molecular engineering, and advanced materials science. His lab's innovations center on implantable biomaterials and devices that enable real-time disease monitoring, localized drug delivery, and regenerative medicine. He heads a $45 million project funded by the Advanced Research Projects Agency for Health (ARPA-H) to create an implantable cancer monitoring and treatment device. Rice University recruited Dr. Veiseh from the Massachusetts Institute of Texas in 2016 with a $2 million Recruitment of First-Time, Tenure-Track Faculty Members award (RR160047).

  CPRIT Scholar Daniel Siegwart, Ph.D., is a professor in the biomedical engineering and biochemistry departments and the Harold C. Simmons Comprehensive Cancer Center at The University of Texas Southwestern Medical Center. He is an inventor on more than 300 patents and pending patent applications, with much of his work in the area of messenger RNA. Scientists use messenger RNA and lipid nanoparticles in common vaccines to train a person's immune system to fight off the virus. Dr. Siegwart's work addresses a major question among the scientific community - whether researchers can apply the same concept to treating diseases such as cancer. Traditional lipid nanoparticles look and act similarly to fats in the bloodstream, which can pose an issue for treating the disease. In one of Dr. Siegwart's inventions, called selective organ targeting, he designed nanoparticles that providers administer intravenously via the bloodstream to go to areas such as the liver or lungs and release the messenger RNA into the tissue, directly targeting the cancer or other diseases. UT Southwestern recruited Dr. Siegwart from the Massachusetts Institute of

Technology in 2012 with a $2 million Recruitment of First-Time, Tenure-Track Faculty Members award (R1212). CPRIT also awarded UT Southwestern and Dr. Siegwart a $900,000 Individual Investigator grant (RP190251) in 2019 to define and enable delivery of microRNA and CRISPR therapeutics for hepatocellular carcinoma.

Stanton F. McHardy, Ph.D., is an associate professor, department of medicinal chemistry and director of the Center for Innovative Drug Discovery at The University of Texas at San Antonio. Dr. McHardy directs laboratory and research programs at UT San Antonio on various drug discovery approaches to neurological diseases, infectious diseases, non-opioid pain, and cancer, including a current research program discovering novel proteolysis targeting chimeras, a molecule that uses our normal cellular machinery to remove unwanted, drug-resistant proteins. Dr. McHardy holds 42 patents in the field of medicinal chemistry and drug discovery. UT San Antonio and Dr. McHardy received two CPRIT Core Facility Support Award grants (RP160844, RP210208) totaling $7.6 million to enhance and expand the Center for Innovative Drug Discovery, which provides researchers in San Antonio and throughout Texas access to pharmaceutical industry level resources, including coordinated medicinal chemistry and high throughput screening technologies, services and expertise that advance drug discovery and development.

Malcolm Brenner, M.D., Ph.D., is the founding director of the Center for Cell and Gene Therapy at Baylor College of Medicine, Texas Children's Hospital, and Houston Methodist Hospital. He holds the Fayez Sarofim Chair and is a member of the Dan L Duncan Comprehensive Cancer Center. Dr. Brenner's group was amongst the first to study the anti-leukemic effects of IL2 following stem cell transplantation and the safety and feasibility of post-transplant immunization. His subsequent studies utilizing gene marking showed that autologous hematopoietic stem cells (HSCs) could contribute to long-term reconstitution after autologous transplant. Collaborating with fellow inductee, Dr. Cliona Rooney, his laboratory developed techniques for depleting alloreactive T cells, transferring them to HSC recipients, and incorporating an inducible caspase 9 suicide gene to enhance safety. Baylor College of Medicine and Dr. Brenner have received three CPRIT research grants (RP110553-AC, RP110553-P1, RP160345) since 2011 totaling $2.7 million.

Cliona Rooney, Ph.D., is a professor in the Center for Cell and Gene Therapy and the Department of Pediatrics, Molecular Virology and Microbiology, and Department of Pathology and Immunology at Baylor College of Medicine. She holds the Thomas J. Rosenbalm, M.D., Presidential Chair and is a member of the Dan L Duncan Comprehensive Cancer Center. Dr. Rooney researches the use of virus-specific T-cells for the treatment of viral diseases and malignancies. She first used EBV-specific T-cells to prevent and treat EBV+ post-transplant lymphoma, then extended this successful therapy to other post-transplant viral infections and to EBV+ malignancies occurring in immunocompetent individuals. She has developed and clinically evaluated strategies that render T cells resistant to inhibition by the tumor microenvironment. CPRIT awarded Baylor College of Medicine and Dr. Rooney two research grants (RP190067, RP240438) totaling $6 million.

Kytai Nguyen, Ph.D., is a professor in the Department of Bioengineering at The University of Texas at Arlington. As a pioneer in bioengineering, Dr. Nguyen creates innovative nanomaterials and drug-delivery systems with the potential to revolutionize health care, particularly in treating cardiovascular diseases and cancer. UT Arlington and Dr. Nguyen received a $250,000 High Impact/High Risk research award (RP210206) from CPRIT in 2021 to develop and evaluate a cell-based nanoparticle system that delivers drugs to cancer cells and tumors while avoiding normal organ side effects.

- The Texas Academy of Medicine, Engineering, Science & Technology (TAMEST) announced December 11 that CPRIT Scholar and pioneering molecular biologist Ilya J. Finkelstein, Ph.D., is the recipient of the 2025 Edith and Peter O'Donnell Award in Biological Sciences for his work enhancing the safety and efficacy of gene editing and uncovering the mechanisms of DNA repair, with the goal of potentially curing diseases. The annual Edith and Peter O'Donnell Awards honor rising star Texas researchers addressing the essential role that science and technology play in society, and whose work meets the highest standards of exemplary professional performance, creativity, and resourcefulness.

  Dr. Finkelstein studies how the cell's protective mechanisms detect and repair genome damage, and how their dysregulation can lead to cancer. Since many cancer therapies target DNA repair pathways, his research will inform future treatments that enhance natural defenses against DNA damage or eliminate cancer cells. His research team is also developing novel approaches to study gene editing CRISPR enzymes and discovered new types of gene editor proteins, aiming to create safer and more effective gene therapies.

  The University of Texas at Austin recruited Dr. Finkelstein from Columbia University Medical Center in 2012 with a $2 million Recruitment of First-Time, Tenure-Track Faculty Members grant (R1214). UT Austin and Dr. Finkelstein subsequently received a $900,000 CPRIT Individual Investigator grant (RP190301) in 2019.

- The Texas Academy of Medicine, Engineering, Science & Technology (TAMEST) announced December 18 that CPRIT Scholar Gerta Hoxhaj, Ph.D., Assistant Professor in Children's Research Institute (CRI) at The University of Texas Southwestern Medical Center, will receive the 2025 Mary Beth Maddox Award and Lectureship for her research in cancer metabolism. TAMEST established the honor, which recognizes women scientists in Texas who bring "new ideas and innovations to the fight against cancer," in 2022, naming the award after former TAMEST Executive Director Mary Beth Maddox, who died from pancreatic cancer. Dr. Hoxhaj will present her work across the state during lectures at four TAMEST member institutions with National Cancer Institute-Designated Cancer Centers.

  UT Southwestern recruited Dr. Hoxhaj from Harvard School of Public Health in 2019 with a $2 million Recruitment of First-Time, Tenure-Track Faculty Members grant (RR190087). UT Southwestern and Dr. Hoxhaj also received a $1.05 million CPRIT Individual Investigator award in 2024 (RP240035). She is a Pew-Stewart Scholar, V Foundation Scholar, American Cancer Society Scholar, and a 2024 recipient of the Vilcek Prize for Creative Promise in Biomedical Science.

- **Genetic Variation Drives Cancer Cell Adaptation to the Rigidity of the Surrounding Extracellular Matrix.** The way tumors change plays a key role in cancer progression, especially in how they spread to other parts of the body (metastasize) and develop resistance to treatments. A better understanding of factors that drive this evolution, such as changes in the stiffness of the surrounding tissue structure - known as the extracellular matrix (ECM) - is critical for improving cancer therapies.

  The ECM, non-cellular material found in all tissues and organs, provides structural support and helps regulate tissue health. As solid tumors grow, scientists have observed that the stiffness of the ECM often changes over time and in distinct locations, but they do not fully understand how these changes interact with the genetic diversity of tumor cells. Using a process called experimental evolution, researchers from Texas A&M University, led by CPRIT Scholar Tanmay Lele, Ph.D., professor in the Department of Biomedical Engineering, and Department of Chemical Engineering, compared genetically diverse tumor cell populations to identical (clonal) tumor cells to study how tumor cells adapt to changes in ECM stiffness.

  Dr. Lele's team found that genetically diverse tumors adapt to softer ECM environments by increasing their growth over time, while clonal cells do not evolve. By using DNA barcoding to track individual cells, the team showed that softer ECM consistently favored certain genetic variants with traits such as increased movement, spreading ability, and the ability to generate force. The researchers linked these adaptations to a process involving the Rho family of proteins, which regulate cell structure, and the relocation of a growth-promoting factor (YAP1) to the cell's nucleus.

  Their research, published on September 20 in *PNAS Engineering*, highlights how the stiffness of the ECM and genetic diversity within tumors work together to influence cancer cell behavior. The findings suggest that variations in ECM stiffness, whether in the original tumor or in metastatic sites, can influence how aggressive tumor cells will become. Future studies on the genetic mechanisms behind these adaptations will provide deeper insights into tumor evolution in changing environments.

  The Texas A&M Engineering Experiment Station recruited Dr. Lele from the University of Florida in 2020 with a $5 million CPRIT Recruitment of Established Investigators grant (RR200043).

- **Stem Cells Reduce Stress to Maintain their Youth.** Although most cells in the human body inevitably age, hematopoietic stem cells (HSCs) maintain their ability to renew throughout most of an organism's lifespan. HSCs, responsible for producing billions of blood cells each day, show delayed signs of aging - such as DNA damage or protein clumping - partly because they can exist in a functionally inactive state for extended periods.

As reported in the November 13 edition of *The Scientist*, CPRIT Scholar Andre Catic, M.D., Ph.D., assistant professor in the Huffington Center on Aging at Baylor College of Medicine, and his team uncovered a new clue about how HSCs maintain their youthful state. In their study, originally published March 9 in *Nature Cell Biology*, the researchers focused on the proteins within HSCs, collectively known as proteome. Maintaining healthy protein levels and preventing harmful clumping (protein homeostasis) is crucial for these long-lived cells. Normally, cells rely on "molecular chaperones," proteins that help other proteins fold correctly and stay functional. Dr. Catic's team identified cyclophilin A, a molecular chaperone highly abundant in HSCs, as a key player in their ability to resist aging.

The scientists found that older HSCs had lower levels of cyclophilin A. Removing this molecular chaperone from young HSCs caused them to age faster, while reintroducing it into older HSCs rejuvenated them and improved their function. The researchers also discovered that cyclophilin A works with specific proteins filled with indetermined structures, called intrinsically disordered regions, which can adopt the necessary configuration to join together other proteins, RNA, and DNA to form complexes in the cell. These proteins regulate cellular stress responses, including stress granules, P-bodies, and nucleoli, which help HSCs endure stress and maintain their function.

Their research suggests that cyclophilin A helps maintain the complex protein networks that protect HSCs from aging. Understanding these mechanisms could have wide-reaching implications—from improving stem cell transplants for cancer and other diseases to uncovering how cells naturally resist aging. It might also provide insights into how the failure of these processes could lead to blood cancers like leukemia.

Baylor College of Medicine recruited Dr. Catic from Harvard University in 2014 with a $2 million CPRIT Recruitment of a First-Time, Tenure-Track Faculty Member award (RR140038). Advanced technologies from several CPRIT-funded core facilities, including genomics, cytometry, and proteomics centers supported his research.

- **Novel Biomarkers Identified in Soft Tissue Sarcomas May Improve Diagnostic and Prognosis Capabilities.** Each year, 13,000 people in the United States are diagnosed with soft tissue sarcomas, and approximately 5,000 will die from the disease. The most common subtype of soft tissue sarcomas is undifferentiated pleomorphic sarcoma (UPS). Two specific types of UPS that affect the skin, atypical fibroxanthoma (AFX) and pleomorphic dermal sarcoma (PDS), are difficult to differentiate during initial biopsies but have significantly different outcomes. AFX rarely spreads to other parts of the body, while deeper UPS tumors spread in more than half of cases.

  Research published in *Molecular Cancer* on November 15 by scientists at The University of Texas Southwestern Medical Center identifies a key protein, COL6A3, as a strong indicator of outcomes in UPS. Led by CPRIT Scholar Gary C. Hon, Ph.D., associate professor in the Cecil H. and Ida Green Center for Reproductive Biology Sciences and the Lyda Hill Department of Bioinformatics, the UT Southwestern team used advanced methods to analyze the gene activity of AFX and PDS tumors at the single-cell level. Because researchers

employing traditional genomic approaches had failed to find reliable markers to predict outcomes for these cancers, the team developed a new protocol for single-cell RNA sequencing on preserved tumor samples and applied spatial transcriptomics to further study one PDS tumor.

Their findings revealed that *COL6A3*, along with another gene, *BGN*, was not only important for distinguishing between AFX and PDS but also predicted survival outcomes in 17 other types of cancer. In studies of independent groups of UPS patients, *COL6A3* emerged as the most reliable predictor of survival and metastasis, outperforming existing gene panels used for sarcomas. The research demonstrated that tumors with higher levels of *COL6A3* had a greater likelihood of metastasis and poorer survival rates, making it a promising new biomarker for guiding treatment in UPS.

UT Southwestern recruited Dr. Hon from the Ludwig Institute for Cancer Research at University of California San Diego in 2014 with the support of a $2 million CPRIT Recruitment of a First-Time, Tenure-Track Faculty Members grant (RR140023). UT Southwestern and Dr. Hon also received an $897,000 CPRIT Individual Investigator Research Award (RP190451) in 2019 that supported this research.

- **New Combination Therapy Option for High-Risk Diffuse Large B Cell Lymphoma**. Diffuse large B-cell lymphoma (DLBCL) is a common and often deadly form of cancer. While researchers have made progress in understanding DLBCL, the standard first-line treatment, known as R-CHOP (a combination of Rituximab immunotherapy and four chemotherapy drugs: cyclophosphamide, doxorubicin, vincristine, and prednisolone), has remained unchanged for over 20 years.

  Scientists at The University of Texas Health Science Center at San Antonio previously discovered that the cyclic-AMP/phosphodiesterase 4 pathway plays a key role in driving the growth of DLBCL. They found that roflumilast, a drug already approved by the FDA for its anti-inflammatory properties, blocks important processes that fuel DLBCL, including signals from the B-cell receptor, the phosphoinositide 3-kinase (PI3K) growth pathway, and the formation of new blood vessels (angiogenesis). This led the researchers to hypothesize that combining roflumilast with R-CHOP could improve treatment outcomes.

  In a recent study, Dr. Ricardo Aguiar and his team conducted a phase 1 clinical trial to assess this idea with high-risk DLBCL patients who had not yet received treatment. These patients had a specific subtype of DLBCL, non-germinal center B-cell like origin, known for its aggressive nature. The study found that combining roflumilast with R-CHOP was both safe and effective. After 44 months of follow-up, 70% of the patients remained free of disease.

  The combined treatment, called Ro+R-CHOP, also significantly reduced VEGFA, a protein that helps tumors grow blood vessels, and PI3K activity, both of which are crucial to DLBCL progression. These promising results suggest that adding roflumilast to standard treatment could improve outcomes for patients with certain high-risk genetic forms of DLBCL.

Published in *MDPI Cancers* on November 18, this research supports further studies to evaluate Ro+R-CHOP in larger, genetically diverse patient groups.

UT Health San Antonio and Dr. Aguiar received a $632,160 CPRIT Individual Investigator grant (RP170146) in November 2016 to study the proangiogenic role of B cell receptor signaling in DLBCL and facilitate the development of new treatment strategies targeting the tumor and its supporting microenvironment. UT Health San Antonio and Dr. Aguiar have also received five other CPRIT awards totaling $3.66 million (RP110200, RP120372, RP140452, RP150277, RP190043) to study B-cell leukemia and lymphoma.

- **SPACe – A Powerful Program for Cell Painting.** Michael Mancini, Ph.D., professor, Department of Molecular and Cellular Biology at Baylor College of Medicine and faculty member of Texas A&M University Health Science Center Institute of Biosciences and Technology, has made a compelling advancement in using high-throughput microscopy to accelerate drug discovery.

  Dr. Mancini's work focuses on morphological profiling, a technique that examines the structure and behavior of cells under different conditions. One of the leading tools in this field is Cell Painting (CP), which uses fluorescent dyes to highlight various cellular structures. Scientists use CP to study how cells respond to genetic changes, drug treatments, and environmental factors. Pharmaceutical companies have also adopted CP for testing thousands of potential drug compounds.

  Analyzing the vast amounts of data generated by CP can be slow and requires powerful computational resources, which limits its accessibility. To overcome these challenges, Dr. Mancini and his team developed a new software platform for analyzing single-cell data: Swift Phenotypic Analysis of Cells (SPACe). Published in *Nature Communications* on November 23, SPACe is an open-source tool written in Python that significantly speeds up and simplifies the analysis of CP data.

  The research team evaluated SPACe using a library of small molecules that impact cell metabolism across seven cancer cell lines, demonstrating its robustness. Compared to existing methods, SPACe offers several advantages. These include processing speed of large datasets using a standard personal computer (approximately 10X faster than current technology), accuracy in mechanism of action recognition, reproducibility across biological replicates, applicability to multiple models, sensitivity to variable cell-to-cell responses, and biological interpretability to explain image-based features.

  By making CP analysis faster, more accurate, and accessible to researchers without access to high-powered computing clusters, SPACe has the potential to transform how scientists conduct drug screening. This user-friendly tool will accelerate the discovery of new treatments for cancer and other diseases, expanding opportunities for researchers worldwide.

  The Texas A&M University System Health Science Center and Dr. Mancini received a $5.8 million CPRIT Core Facility Support Awards grant (RP170719) to establish the Gulf Coast

Consortia Center for Advanced Microscopy and Image Informatics, which supported software development, experimental approaches, and imaging for this project.

- **CPRIT Scholar, Anna-Karin Gustavsson, Ph.D., Innovates in Super-Resolution Imaging in 3D.** Single-molecule localization microscopy is an advanced technique that allows scientists to explore cellular structures at an incredibly detailed nanoscale level. One approach, Exchange-PAINT, uses special DNA tags to label multiple cellular components and images them one at a time, which avoids the distortions that often occur when capturing multiple colors simultaneously. However, Exchange-PAINT requires long imaging times to achieve high resolution, especially when examining multiple targets.

  CPRIT Scholar Anna-Karin Gustavsson, Ph.D., Department of Chemistry, Rice University, and her team developed soTILT3D, an innovative optical imaging platform that provides improved 3D super-resolution imaging and single-particle tracking, to address the Exchange-PAINT issues. The key to soTILT3D's success is its combination of a steerable tilted light sheet, an advanced microscopy technique that illuminates samples with a thin plane of light, and a nanoprinted microfluidic chip. This setup, which uses commercially available components, enables high-density, 3D Exchange-PAINT imaging in thick mammalian cells while reducing background interference, making it more effective for complex samples.

  Published in *Nature Communications* on November 24, the research demonstrated soTILT3D's ability to image lamin B1, a critical structural protein, throughout clusters of stem cells. Using another method called direct stochastic optical reconstruction microscopy (dSTORM), the platform proved effective not only for single cells but also for larger, multi-cellular samples. This versatility shows that researchers can use soTILT3D for a wide range of applications, making it a valuable tool for studying nanoscale cellular structures and molecular behaviors more efficiently and precisely. The new platform simplifies and improves 3D imaging techniques, providing scientists with a powerful and adaptable tool for single-molecule imaging.

  Rice recruited Dr. Gustavsson from Stanford University in 2020 with support from a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR200025).

- **Super-sizing CAR-T cells to Fight Solid Tumors.** CAR T-cell therapy, which reprograms a patient's own immune cells to fight cancer, has shown remarkable success in treating certain blood cancers but has been less effective against solid tumors. Andras Heczey, MD, associate professor in the Department of Pediatrics at Texas Children's Cancer and Hematology Center at Baylor College of Medicine and the Dan L Duncan Comprehensive Cancer Center, and his team have developed a promising new approach to improve CAR T-cell therapy for solid tumors. Their findings, published in *Nature* on November 27, report on a novel treatment in phase 1 clinical trials targeting tumors that express glypican-3 (GPC3), a protein found in certain cancers.

In earlier studies, researchers discovered that adding interleukin-15 (IL-15), a protein that helps T-cells survive and multiply, could significantly boost the effectiveness of CAR T-cell therapies. In this trial, Dr. Heczey's team assessed CAR T-cells targeting GPC3 in two groups: one receiving standard GPC3 CAR T-cells and the other group receiving modified GPC3 CAR T-cells that also produce IL-15.

Patients in the group receiving standard CAR T-cells tolerated the therapy well but showed no significant tumor reduction, with the CAR T-cells only expanding in the body for about two weeks. In contrast, patients in the group that received IL-15-enhanced CAR T-cells saw better outcomes, with 66% experiencing disease stabilization and 33% showing tumor reduction. The IL-15-enhanced cells also expanded significantly more in the body. However, these enhanced cells caused a higher rate of cytokine release syndrome, an inflammatory side effect that providers can manage using specific treatments or a built-in safety switch to deactivate the CAR T-cells when necessary.

Further analysis revealed genetic changes in the CAR T-cells of patients who responded well to the therapy. These cells showed increased activity in immune-signaling genes and reduced activity in certain regulatory genes, allowing them to better survive and fight tumors within the body.

This study demonstrates that IL-15 can make CAR T-cells more effective at targeting solid tumors by enhancing their survival and antitumor activity. It also provides important insights into how these therapies work inside tumors, offering a roadmap for developing safer, more effective CAR T-cell treatments for solid cancers in the future.

CPRIT awarded Baylor College of Medicine and Dr. Heczey and his co-investigators five research grants (RP180674, RP180785, RP190160, RP200584, RP230120) totaling $13 million to support this research.

Personnel

CPRIT has filled 53 full-time equivalent positions, including nine long-term contract employees.

CPRIT Outreach

Staff outreach activities during November and December include:

- At the invitation of David Arthur, CEO of CPRIT grantee Salarius Pharmaceuticals, I spoke at the November 5 meeting of the Executive Association of Houston about CPRIT's mission and our activities.

- Director of Academic Research Dr. Patty Moore presented at the National Council of University Research Administrators (NCURA) Conference in Galveston on November 5.

- On November 6, I met with Kevin Koym, founder and CEO of Tech Ranch Austin about CPRIT's programs. Tech Ranch is a venture accelerator comprised of a global ecosystem of entrepreneurs, businesses, investors, and community leaders.

- Senior Program Manager for Product Development Research Dr. Abria Magee participated in a panel titled "Houston's Cell Therapy Ecosystem: Creating a Holistic Engine to Drive Cell Therapy from Concept to First-In-Human and Beyond at the Society for Immunotherapy of Cancer (SITC) International Conference" in Houston on November 6. The panel included Steve Kean (president & CEO, Greater Houston Partnership), Ross Barrett (general partner, Cancer Focus Fund), Dr. Jason Bock (CEO, CPRIT grantee CTMC), CPRIT Scholar Dr. Christopher Flowers (division head of Cancer Medicine, MD Anderson Cancer Center), Dr. Madan Jagasia (CEO, Obsidian Therapeutics), and Dr. Qasim Rizvi (CEO, KSQ Therapeutics).

- Dr. Magee presented an overview of CPRIT's programs and funding accomplishments on November 7 to Johnson & Johnson's Oncology division. Key leaders from J&J's oncology and innovation teams attended the session, including Dr. Robert Radinsky, Vice President, Oncology Scientific Innovation for North America.

- On November 10-11, CPRIT co-hosted the Researchers RoundUp conference for CPRIT-funded childhood and adolescent cancer researchers held at Pegasus Park in Dallas. Chief Scientific Officer Dr. Le Beau, Dr. Moore, Communications Director Mark Loeffler, Digital Communications Specialist Justin Rand, and I attended. Dr. Le Beau and I spoke, welcoming the group, and providing updates on CPRIT's investment in childhood and adolescent cancers, and future opportunities.

- Deputy Executive and Chief Operating Officer Heidi McConnell and Dr. Magee attended the Rice University Biotechnology Launch Pad tour in Houston on November 11. The event included a meeting with CPRIT Scholar Dr. Omid Veiseh, Texas Medical Center partners, and the launch of Rice University's strategic initiative.

- I met with the Termeer Foundation's Executive Director Catharine Smith and Senior Director of Programs Erica Mawby-Roche on November 13 to discuss CPRIT programs and potential collaborations. The Termeer Foundation, named for former Genzyme CEO Henri Termeer, is a nonprofit organization working to vibrantly connect and empower the world of healthcare innovators.

- Dr. Magee and I met with Louise Dyhrberg, Senior Commercial Advisory, Life Science Sector, with the Danish Consulate, on November 14 regarding opportunities available for companies to relocate to Texas through the CPRIT Product Development program.

- Chief Product Development Officer Dr. Ken Smith, Dr. Magee, and I participated in the "Closing in On Cancer" event hosted by Portal Innovations and Cancer Moonshot at TMC's Helix Park on November 19. I spoke on the panel "Enabling Innovators through Institutional Partnerships and Leveraging Investment," which highlighted CPRIT's role in fostering innovation through partnerships and strategic investments.

- Chief Prevention Officer Ramona Magid attended the American Cancer Society National Colorectal Cancer Roundtable annual meeting held in Fort Worth on November 20-22. The Roundtable reduces the incidence and mortality from colorectal cancer in the United States through coordinated leadership, strategic planning, and advocacy.

- I met with former CPRIT Oversight Committee member Angelos Angelou and Dr. Rahul Pathri on November 22 at Mr. Angelou's International Accelerator office in Austin to discuss upcoming product development opportunities.

- On December 3, Dr. Le Beau attended a National Cancer Institute Joint Meeting of the Board of Scientific Advisors and the National Cancer Advisory Board. The focus of the meeting was to review the current NCI budget and initiatives, new and reissued Requests for Applications, and to provide advice on NCI priorities. Subcommittees also presented initiatives to promote the development of new cancer therapies, and to expand population-based research, epidemiological studies of cancer, and health equity research.

- I delivered a presentation about CPRIT's mission and history at TMC's Neuroscience Summit held at Helix Park on December 4. Dr. Sarah Hein, co-founder and CEO of CPRIT grantee March Bioscience, also spoke to the conference attendees about CPRIT's product development program and her experience as a CPRIT grantee.

- Oversight Committee member Dee Margo attended a dinner on December 4 hosted by the leadership team at Texas Tech University Health Sciences Center El Paso to celebrate the initiation of a formal partnership between Texas Tech Health El Paso and The Center for Clinical & Translational Sciences at The University of Texas Health Science Center at Houston.

- Bisnow Media honored Dr. Magee as Innovator of the Year at Bisnow's "Houston Women Leading Real Estate: A Celebration of Women in Healthcare" on December 5. Bisnow Media, a multi-platform digital media company serving the commercial real estate industry, specializes in news and live events.

- Oversight Committee member Will Montgomery attended the President's Open House at The University of Texas Southwestern Medical Center on December 8. Mr. Montgomery met several CPRIT grantees, who praised CPRIT's work and positive expansive effect on cancer research in Texas and the rest of the nation.

- Dr. Magee, Dr. Smith, and Program Manager for Product Development Dr. Michelle Leeuwon met with representatives from TRIO Pharmaceuticals, including Dr. Kim Lyerly,

Dr. Shiva Bhowmik, and Dr. Reiner Laus on December 9. They discussed CPRIT funding opportunities, eligibility criteria, relocation requirements, and TRIO's clinical development of their lead programs.

- Dr. Smith met with Dr. Lauren Tyra from GPG Ventures, a Texas-based investment firm that has invested in several CPRIT companies, on December 9 to discuss funding opportunities for companies that focus on devices and diagnostics for use in cancer treatments.

- I met with Dr. Cheasty Anderson and James Gray from the American Cancer Society Cancer Action Network (ACS CAN) in CPRIT's office on December 10 to discuss CPRIT's activities. Dr. Anderson is the new managing director of the ACS CAN Gulf Coast region.

- CPRIT Chief Financial Officer Grant Weaver, Ms. McConnell, and I attended the Texas Healthcare Bioscience Institute's (THBI) holiday networking event held in Austin on December 10.

- I met with Martha Brown, Vice Chancellor for State Relations, and Kristina Butts, Vice Chancellor for Governmental Relations, Texas Tech University System, in Lubbock on December 13 to discuss the system's CPRIT-funded projects.

- Throughout November and December, Dr. Magee met with several companies, including Faeth Therapeutics, Sentinel Bio, Oncoswitch, and TMAB Therapeutics, to discuss the CPRIT Product Development application process and timeline. These meetings addressed the anticipated April 2025 release of the product development RFAs.

Legislative Outreach and Preparations for the 89th Legislative Session

The 89th Legislative Session will convene in regular session January 14, 2025, through June 2, 2025. When they arrive in Austin next month, the Texas Senate will have three new members, and the Texas House will have 31 new members. For most of January, the two chambers will take care of organizational matters, make committee appointments, and consider legislation that the Governor has designated as "emergency." The House will elect a new speaker, and the Speaker of the House and Lt. Governor will each identify their top priority issues, designating the legislation with low bill numbers.

Senate Committee on Health & Human Services Interim Charge Report Released

In preparation for the upcoming session, the Texas Senate Committee on Health and Human Services issued their interim report to the 89th Legislature on December 10. Regarding the committee's interim charge addressing cancer prevention and screening and funding adequacy for prevention efforts at CPRIT, the report provided a comprehensive overview of CPRIT, Texas cancer data and statistics, trends in cancer, the COVID-19 public health emergency and cancer, cancer treatments, screening, detection, and prevention. Ultimately, the committee recommended that, "…Policymakers should continue current CPRIT prevention services and

maintain the current structure of funding for investments in medical devices and tests to support earlier cancer detection." You can find the interim charge report here: https://senate.texas.gov/cmtes/88/c610/c610_InterimReport_2024.pdf.

As earlier reported, I testified pursuant to the committee's invitation at their May 14 interim charge hearing. Dr. Ernest Hawk, vice president and head of the division of Cancer Prevention and Population Sciences at The University of Texas MD Anderson Cancer Center, Dr. Manda Hall, Deputy Commissioner of Community Health Improvement at the Texas Department of State Health Services (DSHS), and Dr. David Wiseman, founder of Synechion, also provided invited testimony at the May 14 hearing.

The interim charge provided CPRIT with an excellent opportunity to highlight our grantees' work related to cancer prevention and screenings across the state. Following the hearing, several members of CPRIT staff, including Chief Scientific Officer Dr. Michelle Le Beau, Chief Prevention Officer Ramona Magid, Deputy Executive and Chief Operating Officer Heidi McConnell, and I met with Lt. Governor staff and members and staff of the Senate Committee on Health & Human Services to provide more information about CPRIT's prevention activities, which are critical to our mission of reducing the cancer burden in Texas.

In our discussions with senators and the Senate committee staff following the May 14 hearing, several indicated that they are also interested in the role that the food supply plays in chronic disease. The committee held a hearing on November 13 to take invited testimony on ways that Texas can support a healthier food supply, including ways to better inform consumers and incentivize food producers. The committee also sought recommendations for "reforming the state's health-related research efforts to improve public health through enhanced nutritional awareness, revised pharmaceutical development, and non-pharmacological interventions."

Although the Lt. Governor did not include this issue as a specific interim charge, the interim charge report issued December 10 noted that committee members also asked about the need for additional public awareness on the connections between diet, environmental factors, and cancer incidence. Witnesses suggested that DSHS could implement additional data points for collection in its cancer registry for incidence rates for early-onset cancers with an emphasis on diet profile, lifestyle, alcohol use, and environmental exposures, including the impacts of COVID-19. We will monitor this issue as it develops during the legislative session and keep you updated.

Legislator Meetings

- I met with Alvaro Diaz, Legislative Director for Senator Nathan Johnon on November 7 to discuss CPRIT's activities and the upcoming legislative session.

- I met with Sen. Kelly Hancock on November 12 to discuss CPRIT's activities and the upcoming legislative session.

- Ms. McConnell and I met with Sen. Pete Flores on November 20 to provide an update on CPRIT's activities and the upcoming legislative session.

- We have a meeting scheduled with Sen. Sarah Eckhardt on January 8.

We will continue to meet with state senators, state representatives, and their staff to update members on CPRIT's activities.

Filed Legislation

November 12 was the first day that Texas state legislators could begin filing bills for consideration during the 89th Legislative Session. As of December 30, legislators have filed 1,699 bills in the House and 681 bills in the Senate, for a total of 2,380 bills. Legislators will submit thousands more bills by the March 14, 2025, bill-filing deadline.

It appears that legislators have not filed any bills at this time that directly affect CPRIT or CPRIT's enabling statute, Texas Health & Safety Code Chapter 102.

Other notable legislation includes:

- SB 124
  Senator Bob Hall filed legislation relating to hospital patients' rights and hospital policies and procedures. The proposed legislation requires the hospital to adopt and implement a written policy ensuring a hospital patient's rights. Included in several enumerated rights proposed in the legislation is the right of a terminally ill patient to access and use certain investigational drugs, biological products, and devices that are in clinical trials in accordance with Texas' Right to Try Act (Texas Health & Safety Code Chapter 489).

- SB209/HB1268
  Senator Royce West and Representative Angie Chen Button filed legislation relating to the creation of the Texas Technology and Innovation Program within the Office of the Governor's Economic Development and Tourism Division. Under the proposed legislation, companies headquartered in Texas that qualify for and receive grants or contracts through the federal Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) programs would receive an additional State of Texas matching grant. With 345 Texas companies receiving SBIR/STTR funding in 2023, Texas ranks among the top ten states for attracting SBIR/STTR funding. However, according to the Texas Healthcare and Bioscience Institute (THBI), 34 states already have existing matching programs, and those states are using matching incentives to attract Texas companies to relocate.

- HB 185/HJR 24
  Representative Senfronia Thompson filed legislation to establish the Mental Health and Brain Research Institute of Texas (MBRIT), modeled on CPRIT. This proposed bill is the same or similar to CPRIT's enabling statute and appears to be the same as the proposed legislation filed last session and passed by the House of Representatives. There is not a Senate bill companion filed at this time. Rep. Thompson also filed a house joint resolution to amend the Texas Constitution authorizing the Texas Comptroller to transfer $3 billion from

the general revenue fund to the MBRIT fund. This transfer would serve as the source of funding for MBRIT's grants and operations.

- HB 975
  Representative Brian Harrison filed legislation relating to the "right to try" cutting-edge treatments for patients with life-threatening or severely debilitating illnesses.

- HB1302/HJR 90
  Representative Richard Raymond filed legislation to create the Alzheimer Prevention and Research Institute of Texas, modeled on CPRIT. This proposed bill is similar to CPRIT's enabling statute. There is not a Senate bill companion filed at this time. Rep. Raymond also filed a house joint resolution to amend the Texas Constitution authorizing the Texas Comptroller to transfer $3 billion from the general revenue fund to the Alzheimer Prevention and Research Institute of Texas to serve as the source of funding for the agency's grants and operations.

Lt. Governor Dan Patrick issued a press release on November 18 announcing a new major legislative initiative for the Texas Senate, the Dementia Prevention Research Institute of Texas (DPRIT). According to Lt. Governor Patrick, the legislature will structure DPRIT like CPRIT and fund it for a decade. In his press release, the Lt. Governor noted:

> "…*One of the most successful existing health programs ever created in Texas is the Cancer Prevention Research Institute of Texas (CPRIT). CPRIT is a model of what a state can do in the area of medical research on a specific disease. CPRIT's only focus is cancer. The state originally funded CPRIT for a decade, which was the key to attracting world-renowned leaders in cancer research to Texas*."

There is no DPRIT legislation filed as of December 30. I will keep you updated.

Upcoming Events

There are upcoming events related to CPRIT, CPRIT grantees, or cancer that may be of interest to Oversight Committee members. Please contact me or the appropriate staff if you would like more information about an event or meeting.

January 9	Product Development Advisory Committee meeting (virtual)
January 27	Accelerator for Cancer Therapeutics (ACT) Bootcamp Week (Houston) *I will attend the first day of Bootcamp Week for the 2025 ACT program cohort and speak about CPRIT's mission and our role in advancing cancer therapeutics toward commercialization at the "Lunch and Learn."*
January 27	Advisory Committee on Childhood Cancer monthly meeting (virtual)
January 31	ACS-CAN Policy Meeting (Houston); several CPRIT grantees will speak

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of December 12, 10 entities had not filed 12 academic research reports, 5 prevention reports, and 3 product development reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 246 second-level reviews of grantee Financial Status Reports (FSRs) in November and December. Forty-one FSRs (17%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Compliance specialists performed four enhanced desk-based financial monitoring reviews in November and December. Desk reviews confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. Desk reviews also aid in the identification of potential problems and technical assistance issues for follow-up during an onsite visit, as well as areas of non-compliance and grantee performance issues. Compliance specialists are collaborating with two grantees to address enhanced desk review findings.

Onsite Reviews

CPRIT completed six onsite reviews in November and December. Onsite reviews are the most extensive monitoring activity conducted by CPRIT and include virtual or field visits led by compliance grant monitoring staff. CPRIT monitors the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and compliance with single audits during onsite reviews. Onsite monitoring enables CPRIT compliance staff to assess a grantee's capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists are collaborating with two grantees to address on-site review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual attestation form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Texas Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or onsite review. As of December 12, 22 of the 63 grantees have submitted their annual compliance attestation. Grantees have until December 31 to submit the completed attestation. As part of the annual attestation process, product development grantees must submit documentation demonstrating compliance with the Texas location criteria, pursuant to Texas Administrative Code §701.19.

Match Expenditures Review

CPRIT requires academic research and product development research grantees to show that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as "CPRIT's matching funds requirement," requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT's statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.

Product development grantees, as well as those academic research grantees whose indirect cost rate credit does not fully offset the required match, must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed five annual match expenditure reviews in November and December. The total amount of match expenses reviewed by compliance staff for FY 2025 is $24,608,679.48. CPRIT staff have identified no unallowable match expenses for FY 2025.

Academic Research Program Update

Recruitment FY 2025 Update

CPRIT's Application Receipt System (CARS) opened for the third cycle of FY2025 applications on October 22 and closed on November 20. The Scientific Review Council reviewed these applications on December 12. Dr. LeBeau will present the recommended applications to the Oversight Committee in February 2025.

FY 25 Cycle 3 Mechanism	Received	Requested
Recruitment of Established Investigators	1	$6,000,000
Recruitment of First-Time, Tenure Track Faculty Members	4	$6,500,000
TOTAL	**5**	**$12,500,000**

Academic Research FY 2025 Review Cycle 2 (25.2)

CPRIT posted six FY25.2 RFAs on August 28. CPRIT's CARS opened for applications on September 18 and closed on December 10. FY25.2 RFAs included three RFAs designed for institutions eligible for the Texas Regional Excellence in Cancer (TREC) awards designed for institutions with a growing cancer research funding base. The TREC awards include the reissue of a Pilot Project Award for early-stage projects, as well as two new TREC RFAs to provide support for Investigator-Initiated Research Awards and for Core Facility Support Awards to advance innovative research projects and to bring new state-of-the-art technologies to the institution's investigators. CPRIT will conduct the Virtual Peer Review in March 2025. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in May 2025.

Academic Research FY 2025 Review Cycle 1 (25.1)

CPRIT posted the following FY25.1 RFAs on February 22. CPRIT's Application Receipt System (CARS) opened for applications on March 19 and closed on June 11. CPRIT conducted the Virtual Peer Review in October 2024. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in February 2025.

FY 25 Cycle 1 Mechanism	Apps	Funds Requested
Individual Investigator Research Award (IIRA)	220	$196,400,895
IIRA for Computational Systems Biology of Cancer	29	$29,833,203
IIRA for Cancer in Children and Adolescents	36	$42,160,677
IIRA for Prevention and Early Detection	21	$24,022,601
IIRA for Clinical Translation	26	$41,025,711
IIRA for Early Onset Cancers	13	$11,379,861
Collaborative Action Program (competitive renewal)	1	$3,000,000
TOTAL	**346**	**$347,822,948**

Product Development Research Program Update

Product Development FY 2025 Review Cycle 2 (25.2)

The Product Development Research team is working with GDIT to prepare and release the Competitive Cost Adjustment request for applications (RFA) that the Oversight Committee approved at its November meeting. Previously funded CPRIT companies that have substantially completed current contract goals and objectives and demonstrate a compelling justification for targeted CPRIT funds to expand their project and attract additional investment are eligible to apply. The process will be competitive, peer-reviewed, and will include a range of awards, some of which may be less than one million dollars. CPRIT plans to release these RFAs in January,

with award recommendations presented for consideration at the May 21, 2025, Oversight Committee meeting.

Prevention Program Update

Prevention FY 2025 Review Cycle 2 (25.2)

The prevention program released three RFAs on August 26 for the second review cycle of FY 2025. CPRIT received 21 applications by the December 5 deadline. Peer review will take place in February 2025. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in May 2025.

Cycle 25.2 Mechanism	Apps	Funds Requested
Primary Prevention of Cancer	8	$9.41 M
Cancer Screening and Early Detection	12	$22.02 M
Dissemination of CPRIT-Funded Cancer Control Interventions	1	$450,000
TOTAL	**21**	**$31.88 M**

Advisory Committees

- The Geographic Diversity Advisory Committee met on November 1.
- The Advisory Committee on Childhood and Adolescent Cancers held an in-person meeting in Dallas at the Researcher's RoundUp on November 11.
- The Product Development Advisory Committee will meet on January 9.
- The Advisory Committee on Childhood Cancer will hold their monthly meeting January 27.

Operations and Finance Update

CPRIT FY 2024 Financial Audit

CPRIT accountant Michelle Huddleston led the finance team's efforts to prepare the FY 2024 Annual Financial Report (AFR) and submitted the unaudited financial statements in accordance with the requirements of Texas Government Code, Section 2101.011. CPRIT provided the AFR to the Comptroller, State Auditor's Office, Governor's Office, Legislative Budget Board, Legislative Reference Library, and Texas State Library on November 1.

Crowe LLP has completed the audit of CPRIT's FY 2024 AFR. CPRIT staff, including Deputy Executive and Chief Operating Officer Heidi McConnell, Operations Manager Lisa Nelson, and CPRIT accountants Michelle Huddleston and Donna Cooper, among others, coordinated closely with the Crowe audit team to facilitate their understanding of CPRIT's programs and IT systems and provided the extensive documentation required for Crowe to evaluate the accuracy of the

agency's financial statements. Crowe presented the draft audit report at a meeting on December 5 with the Audit Subcommittee, who accepted the report on behalf of the Oversight Committee. Crowe delivered the final report on December 13, and CPRIT submitted it to the same offices that received the AFR.

Procurement

CPRIT Contract Specialist Don Brandy is finalizing the conference planning and coordinating services contract award to Innovation Event Management LP following the approval of the contract at the November 20 Oversight Committee meeting. In addition, CPRIT is currently developing a statement of work for data audit services for the agency's Wellspring intellectual property database.

Upcoming Subcommittee Meetings

I have listed below the subcommittee meetings that CPRIT will hold in advance of the February 19, 2025, Oversight Committee meeting. CPRIT staff will make the subcommittee agenda and meeting materials available in Govenda one week prior to each meeting.

Board Governance	February 6 at 10:00 a.m.
Audit	February 10 at 12:00 p.m.
Prevention	February 11 at 12:00 p.m.
Academic Research	February 12 at 12:00 p.m.
Product Development	February 13 at 10:00 a.m.

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CPRIT has awarded **2,038** grants totaling **$3.74 billion:**

- 311 prevention awards totaling $394.2 million
- 1,727 academic research and product development research awards totaling $3.35 billion

Of the $3.35 billion in academic research and product development research awards,

- 33.6% of the funding ($1.12 billion) supports clinical research projects.
- 22.8% of the funding ($762.1 million) supports translational research projects.
- 29.0% of funding ($971.4 million) supports recruitment awards.
- 11.9% of the funding ($397.2 million) supports discovery stage research projects.
- 2.7% of funding ($91.6 million) supports training programs.

CPRIT has 3 open Requests for Applications (RFAs)

- 3 Academic Research Recruitment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR JANUARY 2025
DATE:	FEBRUARY 3, 2025

Topics in this memo address CPRIT activities in January, including preparations for the February 19 Oversight Committee meeting, recent milestones in our fight against cancer, CPRIT's 2024 Annual Report, a staffing summary, the 2025 legislative session, outreach efforts, upcoming CPRIT-related events, and updates from Compliance, Programs, and Operations.

Planning for the February 19 Oversight Committee Meeting

The Oversight Committee will meet on Wednesday, February 19, in the Barbara Jordan Building at 8:30 a.m. We will have a full agenda with grant award recommendations, an annual report from the Advisory Committee on Childhood Cancer, and a product development grantee presentation. Please notify me as soon as possible if you are unable to attend the February 19 meeting or have schedule constraints that require you to arrive at the meeting after 8:30 a.m. or leave prior to 12:30 p.m.

You will receive an email from CPRIT by February 7 with a link and password to access the Program Integration Committee's award recommendations via the grant award portal. The portal has a summary of the award slates, as well as supporting documentation for each proposed award, including the application, CEO affidavit, summary statement, and grant pedigree. Please allow time to complete the conflict-of-interest checks and review the supporting material.

I have attached a draft Oversight Committee meeting agenda. We will post the final agenda for the meeting by February 11. You will receive an electronic copy of the agenda packet on February 12. Hard copies of the agenda and award packet will be available at the meeting.

Recent Milestones in the Fight Against Cancer

<u>CPRIT Grantees in the News</u>

- Veronica Ajewole, PharmD, BCOP, associate professor of Pharmacy Practice at Texas Southern University and oncology clinical pharmacist at Houston Methodist Hospital, joined KTSU-FM Tiger Thursday on October 17 to talk about her breast cancer prevention initiatives.

Dr. Ajewole is the program director of Texas Southern's Breast Cancer Screening and Prevention Center (BCSPC), and their goal is to improve access to annual mammogram screening and prevention services to eliminate disparities among African American women. The BCSPC provides no-cost mammograms, patient navigation/barrier reduction services, and evidence-based, culturally appropriate breast cancer awareness and education services for traditionally underserved women with higher risk for breast cancer.

In 2021, Texas Southern and Dr. Ajewole received a $1 million CPRIT Prevention grant (PP210049) to expand the BCSPC. Through this grant, CPRIT funds helped to expand the BCSPC by creating partnerships with Houston Methodist, community centers, churches, and libraries, as well as collaboration with Federally Qualified Health Centers, which are instrumental to recruiting and outreach efforts.

- Houston Methodist announced January 13, 2025, the appointment of renowned cancer physician-scientist Jenny Chang, M.D., MBBChir, MHCM, to serve as executive vice president, president and CEO, and chief academic officer of the Houston Methodist Academic Institute. The institution selected Dr. Chang, the Emily Herrmann Presidential Distinguished Chair in Cancer Research, and professor in the Department of Medicine, following a national search. She succeeds H. Dirk Sostman, M.D., FACR, who will retire next month after two decades of leadership at Houston Methodist.

  In her more than 15 years at Houston Methodist, Dr. Chang helped transform the Dr. Mary and Ron Neal Cancer Center into one of the top 20 ranked cancer centers in the country, according to the *U.S. News & World Report* rankings. In the last five years, Dr. Chang has served as Houston Methodist Academic Institute's chief clinical science officer and strengthened cancer clinical trials across Houston Methodist's system of eight hospitals. She will lead efforts to expand clinical and translational research and education in digital health, robotics, and bioengineered therapeutics.

  Dr. Chang's research focuses the characteristics of cancer-causing cells – the cancer stem cells. Her recent work on the intrinsic therapy resistance of cancer stem cells, and the role of targeting inflammatory pathways to change the tumor immune microenvironment has led to a better understanding of how specific cancer treatments work and ways to improve their effectiveness in breast cancer.

  The Methodist Hospital Research Institute and Dr. Chang received a $900,000 CPRIT Individual Investigator Research grant (RP170466) in 2017, and a $250,000 High-Impact, High-Risk grant (RP220650) in 2022 to support her research on breast cancer.

- On January 15, 2025, the American Society for Clinical Investigation (ASCI) announced their newly elected members. CPRIT Scholar Wen Jiang, M.D., Ph.D., is among the elected members who represent excellence across the breadth of academic medicine. ASCI is among the few organizations focused on the special role of physician-scientists in research, clinical

care, and medical education, as well as leadership positions in academic medicine and the life sciences industry.

Dr. Jiang, an associate professor with tenure in the Department of Radiation Oncology at The University of Texas MD Anderson Cancer Center, cares for patients with primary and secondary central nervous system tumors. His research focuses on the understanding of immune suppressive mechanisms within solid tumors and identifying novel therapeutic strategies to overcome immune escape.

The University of Texas Southwestern Medical Center recruited Dr. Jiang in 2018 with the support of a $2 million CPRIT First-Time, Tenure-Track Scholar Award (RR180017). He joined MD Anderson in 2021, and CPRIT subsequently awarded the institution two CPRIT High-Impact, High-Risk grants (RP220553, RP240493) totaling $500,000, to support his research improving cancer immunotherapies.

- On January 15, 2025, the Texas Academy of Medicine, Engineering, Science and Technology (TAMEST) and Lyda Hill Philanthropies announced the recipients of the 2025 Hill Prizes. David Mangelsdorf, Ph.D., chair and professor in the Department of Pharmacology, professor in the Department of Biochemistry, and the Raymond and Ellen Willie Distinguished Chair in Molecular Neuropharmacology at The University of Texas Southwestern Medical Center, received the Hill Prize in Biological Sciences for his proposal to explore a novel vulnerability in the signaling pathway that governs soybean cyst nematode (SCN) infection in soybeans.

  Dr. Mangelsdorf and Dr. Kliewer work together in a joint laboratory which focuses on nuclear receptor regulation of metabolism. Their early work led to the identification of the functions of many orphan nuclear receptors uncovering potential therapeutic targets for diseases such as cholestasis, type 2 diabetes, and obesity.

  Dr. Mangelsdorf led a CPRIT-sponsored Multi-Investigator Research Award focusing on the development of nuclear receptors and their co-regulators as diagnostic and therapeutic targets of breast and lung cancer (RP101252, RP120732, $12.8 Million).

<u>Notable CPRIT-Supported Research and Prevention Accomplishments</u>

- **CPRIT TREC Funding Leads to Pivotal Insights into Mechanism Conferring Therapeutic Resistance in Prostate Cancer.** Androgen deprivation therapy that includes androgen receptor signaling inhibitors, such as enzalutamide, is a common treatment for advanced prostate cancer. Following a period of response, patients develop resistance to androgen deprivation therapy and the disease progresses to castration resistant prostate cancer. However, scientists do not fully understand the specific molecular mechanism(s) driving this process.

  A new study by Srinivas Nandana, Ph.D., an assistant professor in the Department of Cell Biology and Biochemistry at Texas Tech University Health Sciences Center, reported in *Oncogene* on December 20, 2024, found that a key protein, TBX2, helps prostate cancer

become resistant to treatment by switching the cancer's survival strategy, allowing it to bypass the androgen receptor and continue growing.

Dr. Nandana and his colleagues previously reported that TBX2 plays a key role in the progression from prostate cancer to castration resistant prostate cancer and to bone metastatic castration resistant prostate cancer. In this study, the investigators genetically modulated TBX2 expression in cell line models of human prostate adenocarcinoma, castration resistant prostate cancer, and enzalutamide-resistant castration resistant prostate cancer. They found that TBX2 reduces the activity of the androgen receptor, the usual target of hormone therapy, while increasing the activity of a different receptor, the glucocorticoid receptor, which resulted in enzalutamide resistance.

The team confirmed the relationships observed between TBX2, the androgen receptor, and the glucocorticoid receptor in cell line models by the analysis of their activities in prostate cancer samples from patients. Next, the investigators sought to determine whether disrupting the function of TBX2 could prevent the loss of function of the androgen receptor, creating a potential therapeutic option. They targeted a protein binding partner of TBX2 - LSD1 - with an inhibitor, SP2509, which blocks a key partner of TBX2. This drug successfully disrupted TBX2's ability to switch the cancer's survival pathway, offering a potential new strategy to overcome treatment resistance in castration resistant prostate cancer.

Taken together, this study reveals a new molecular model of castration resistant prostate cancer where interactions between three key proteins - TBX2, the androgen receptor, and the glucocorticoid receptor - could help predict whether a patient's cancer will become resistant to the drug enzalutamide. While directly blocking the glucocorticoid receptor is not practical clinically due to serious side effects, the study suggests an alternative approach: targeting LSD1, a protein that helps TBX2 function. Blocking LSD1 may indirectly suppress the glucocorticoid receptor and restore sensitivity to enzalutamide, offering a potential new treatment strategy for castration resistant prostate cancer.

The Texas Tech University Health Sciences Center received a $6 million CPRIT Texas Regional Excellence in Cancer Award (RP210154, PI: Dr. C. Patrick Reynolds) that provided research project support to Dr. Nandana for this research.

- **New biomarker Predicts Improved Outcomes With Dose-Dense Chemotherapy in ER+ Breast Cancer.** Identifying clinical features that help predict an individual's response to therapy is a vital area of cancer research. A new biomarker study led by CPRIT grantee W. Fraser Symmans, MB.ChB., professor, Department of Pathology, Division of Pathology/Lab Medicine at The University of Texas MD Anderson Cancer Center, provides novel insights into how dose-dense chemotherapy can improve survival for some patients with node-positive, estrogen receptor-positive (ER+) breast cancer. Dose-dense chemotherapy is a treatment plan in which researchers administer drugs with less time between treatments than in a standard chemotherapy plan.

In the study reported January 2, 2025, in the *Journal of Clinical Oncology*, the researchers analyzed 12-year follow-up outcomes data from the Phase III CALGB 9741 trial, which included nearly 2,000 patients with node-positive, early-stage breast cancer. The research team also correlated the sensitivity to endocrine therapy (SET2,3) test index with outcomes by evaluating 682 banked RNA samples from ER+ cancers. The SET2,3 test, developed in Dr. Symmans' laboratory, uses a biomarker to measure how well a tumor might respond to endocrine (hormone-blocking) therapy, identifying the patients most likely to benefit from dose-dense chemotherapy.

The results showed that dose-dense chemotherapy, given every two weeks instead of the standard three-week schedule, improved disease-free survival by 20% and overall survival by 15%. Using the SET2,3 biomarker test, the researchers discovered that 40% of the patients with a low endocrine activity index benefited the most from this treatment.

Their findings show that dose-dense chemotherapy is more effective than the standard schedule for women with early-stage ER+ breast cancer and low endocrine activity index. The key finding was that low endocrine activity in the cancer, rather than tumor size, cancer type, or menopausal status, predicted better outcomes with this treatment. This underscores the importance of biomarker-driven approaches in personalizing cancer treatment to ensure patients receive the most effective therapy for their specific tumor biology.

MD Anderson and Dr. Kelly Hunt received a $6 million CPRIT Multi-Investigator Research Awards grant (RP180712) in 2018 to support this ER+ breast cancer research. MD Anderson and Dr. Symmans also received a $6 million CPRIT Multi-Investigator Research Awards grant (RP160710) in 2016 to support a randomized clinical trial platform with translational studies to overcome resistance in triple negative breast cancer.

- **New Link Between Heart Disease and Risk for Advanced Breast Cancer.** Cardiovascular disease and cancer are the two leading causes of death in the United States. Research led by CPRIT Scholar Kevin Nead, M.D., assistant professor in the Departments of Epidemiology and Radiation Oncology at The University of Texas MD Anderson Cancer Center, shows that patients diagnosed with late-stage or metastatic breast cancer have a statistically significant increased risk of pre-diagnosis cardiovascular disease compared to those diagnosed with cancer at an earlier stage.

  The population-based case-control study published January 2, 2025, in *JAMA Network Open* analyzed data from more than 19,000 individuals included in the Surveillance, Epidemiology, and End Results (SEER)-Medicare linked databases from 2009-2020. The researchers compared the presence of cardiovascular disease (e.g., coronary heart disease, stroke, high blood pressure, heart failure, hypertension, arterial disease) between patients with early (stage I-II) and advanced (stage III-IV) cancer.

  The research revealed that almost half of the individuals included in the study had cardiovascular disease. The patients with advanced breast cancer at diagnosis were 10% more likely to have had pre-existing cardiovascular disease. Additionally, patients with a specific

breast cancer subtype, hormone receptor-positive (HR+)/HER2-negative (HER2-), were most likely to have pre-existing cardiovascular disease (11%). The increased risk was present both for patients with locally advanced and metastatic breast cancer. The five-year relative survival rate for metastatic HR+/HER2- breast cancer is only 34%, underscoring the need for prevention and early detection.

These findings may be specific to HR+/HER2- disease. Researchers will conduct more studies to confirm these findings and test interventions to improve outcomes, including personalized cancer screening, to detect the disease at an earlier, more treatable stage.

MD Anderson recruited Dr. Nead from the University of Pennsylvania in 2019 with the support of a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR190077).

- **"All for Them" Project Team Members Share Key Lessons, Implementation Strategies for Increasing HPV Vaccinations at National and International Conferences.** The University of Texas Health Science Center at Houston School of Public Health and program director Paula Cuccaro, Ph.D., assistant professor in the Department of Health Promotion and Behavioral Sciences, runs the CPRIT-funded program, "All for Them," in partnership with school districts, healthcare provider partners, and other community organizations. The All for Them initiative assists schools in planning, implementing, and evaluating comprehensive human papillomavirus (HPV) immunization clinics to help adolescents and their families access life-saving resources and accurate immunization information

  In November 2024, Dr. Cuccaro and her team presented three posters conveying All for Them program implementation and dissemination work at the 36th International Papillomavirus Conference in Edinburgh, Scotland. The posters highlighted key lessons from their project for others in the field to use to introduce the All for Them program in their communities, including effective implementation strategies, the benefits of educating school nurses about HPV and vaccine communication, and how implementation mapping helps create tools for schools and healthcare providers.

  Dr. Cuccaro presented their dissemination project at the 17th Annual Conference on the Science of Dissemination and Implementation, which the National Institutes of Health and Academy Health co-hosted in Washington, D.C., on December 8 - 11, 2024. She served as a panelist for the session "Implementation Science Considerations for Underserved Populations." She shared how the All for Them project team used implementation mapping to design their dissemination strategy, which they transitioned to a statewide project that is now in the pilot phase with diverse populations across Texas.

  UTHealth Houston received four CPRIT Prevention grants (PP170046, PP200017, PP230033, PP240030) totaling $6.4 million in support of the All for Them program.

- **Molecular Analysis of Pediatric Brain Tumors Reveals "Context is Everything."** Medulloblastomas are one of the most common brain tumors in children. Scientists know that

certain genes play a key role in driving these cancers, especially in specific types of medulloblastomas. There are a number of well-known driver genes for medulloblastoma, particularly sonic hedgehog pathway genes in sonic hedgehog medulloblastoma. However, scientists do not understand group 4 (G4) medulloblastoma well. A new study reported on January 3 in *Nature Genetics* sheds new light on the etiology and treatment of G4 medulloblastomas.

Led by CPRIT Scholar Michael D. Taylor, M.D., professor in the Department of Pediatrics, Section of Pediatric-Hematology, Director of the Pediatric Brain Tumor Research Program, and chair of Pediatric Neuro-Oncology at Baylor College of Medicine, the research team studied two types of medulloblastoma, G4 and sonic hedgehog, which likely arise from a common cell of origin in the developing cerebellum. The team discovered that the ZIC1 transcription factor gene drives their growth, but by different mechanisms.

In 60% of cases of G4 medulloblastoma, ZIC1 exhibits loss-of-function due to genetic mutations, subchromosomal deletions, or other mechanisms. In contrast, in sonic hedgehog medulloblastoma, ZIC1 becomes overactive due to gain-of-function mutations and copy number gains seen in 20% of cases. This means that while ZIC1 slows down tumor growth in G3 and G4 medulloblastomas, Z1C1 makes the cancer more aggressive in sonic hedgehog medulloblastomas.

The ZIC1 transcription factor gene is a stark example of how the same gene can have distinct driver mechanisms in highly similar cancers depending on their specific lineage of origin. In one subgroup, ZIC1 mutations produce active proteins that are potentially good targets to inhibit, whereas in the other group, a loss-of-function mutation necessitates restoring its function as a potential therapeutic avenue.

Baylor College of Medicine recruited Dr. Taylor from the Hospital for Sick Children in Toronto in 2022 with the support of a $6 million CPRIT Recruitment of Established Investigators grant (RR220051).

- **Study by The University of Texas at El Paso Researchers Sheds Light on Barriers That Hispanic Individuals Face Regarding HPV Vaccination.** The human papillomavirus (HPV) causes cancers that impact a disproportionate number of Hispanic individuals, including head and neck cancer and cervical cancer. An HPV vaccine is available that protects against nine types of HPV and 90% of HPV-associated cancers. The U.S. Centers for Disease Control and Prevention recommends the HPV vaccine for everyone between 9–45 years old, but uptake of the vaccine varies among ethnic populations. To increase HPV vaccination rates, it is important to identify trusted voices who can credibly recommend vaccinations and help shape better public health efforts related to HPV, ultimately reducing cancer disparities.

  Gabriel Frietze, Ph.D., assistant professor in the Department of Pharmaceutical Sciences, and the Border Biomedical Research Center at The University of Texas at El Paso, led a CPRIT-supported research study using a qualitative approach to identify who Mexican American

parents of children aged 11–17 trust most to disseminate HPV vaccine information. To gather insights, researchers conducted three pilot focus groups that included Mexican American parents in El Paso who were 18 or older, spoke English, and had a child between 11 and 17

All three focus groups identified pediatricians, registered nurses, and pharmacists as the most trusted sources of information. Findings from this study, reported on January 7, 2025, in *The International Journal of Environmental Research and Public Health*, have implications for designing public health interventions that leverage pediatricians, registered nurses, and pharmacists to promote the HPV vaccine among parents. The study, which focuses on Hispanic people of Mexican origin, provides new insights into the unique barriers that Hispanic individuals face regarding HPV vaccination.

The University of Texas at El Paso received a $5.9 million CPRIT Texas Regional Excellence in Cancer Award (RP210153) in 2021, which provided support to Dr. Frietze for this research.

- **Researchers Identify Potential Markers of Exceptional Immunotherapy Responses in Renal Cell Carcinoma**. Renal cell carcinoma is the most common form of kidney cancer. Doctors often treat metastatic renal cell carcinoma patients with immune checkpoint inhibitors as part of their treatment, but only a small subset of patients achieve long-term remissions or cures. Historically, the molecular basis for a significantly better outcome than the typical response rate (also known as "exceptional response") to immunotherapy in metastatic renal cell carcinoma was unclear. However, new research reported in the January 9, 2025, issue of *Nature Cancer* has identified potential predictors of exceptional response to immunotherapy in this disease.

  To identify molecular biomarkers for these exceptional responders and to help predict the patients who will benefit most, a research team led by CPRIT Scholar Sachet Shukla, Ph.D., an assistant professor, Department of Hematopoietic Biology and Malignancy, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, analyzed pre-treatment tumor samples. They matched germline (non-malignant) samples from patients treated with standard-of-care immunotherapies (combination of PD1/PDL1 and CTLA-4 inhibitors) compared to a combination of PD1/PDL1 and vascular endothelial growth factor (VEGF) receptor inhibitors.

  The researchers identified several potential drivers of exceptional responses. In the immunooncology-only cohort, those who responded well had a higher number of tumor-specific markers, suggesting a strong immune response driven by T cells. In the immunooncology/VEGF cohort, participants with exceptional responses displayed strong enrichment of B cell signaling-related pathways, tertiary lymphoid structure signatures, and evidence of increased metabolic activity.

  The research team must validate these biomarkers before they are clinically viable. Nonetheless, this multi-institutional study suggests that therapeutic combinations that elicit both T cell-directed and B cell-directed antitumor immunity may be important to achieve exceptional benefit to immunooncology-based treatment in metastatic renal cell carcinoma. It

also lays the foundation for better understanding the mechanisms underlying exceptional responses in this subset of patients.

MD Anderson recruited Dr. Shukla in 2022 from the Dana Farber Cancer Institute at Harvard University with the support of a $2 million CPRIT First-Time, Tenure-Track Faculty Members grant (RR220009).

- **Promising Study by CPRIT Grantee Aaron Thrift, Ph.D., Identifies New Predictive Markers for Liver Cancer.** Hepatocellular carcinoma, the most common type of liver cancer, is a leading cause of death worldwide. The incidence and mortality rate of hepatocellular carcinoma in the United States has increased rapidly over the past two decades, with Texas experiencing the fastest-growing incidence rate in the nation. Despite advancements in treatment, doctors are able to cure fewer than 10% of hepatocellular carcinoma patients, and less than one in five patients with hepatocellular carcinoma survive more than five years.

  Cirrhosis is the precursor to more than 80% of the hepatocellular carcinoma cases diagnosed in the United States. Understanding the mechanism by which cirrhosis transitions to hepatocellular carcinoma and identifying key biomarkers are crucial steps to developing effective screening, risk stratification, and prevention strategies necessary for improving dismal survival rates.

  Study results reported by CPRIT grantees in the January 15, 2025, edition of *Cancers* could lead to a new approach to reduce the number of people dying from hepatocellular carcinoma. Led by Aaron Thrift, Ph.D., an associate professor in the Departments of Medicine, and Epidemiology and Population Science at Baylor College of Medicine, the research team examined DNA methylation in hepatocellular carcinomas. DNA methylation is an epigenetic modification that controls gene expression and chromosomal stability without changing the DNA sequence. Scientists have observed changes in methylation patterns in many solid cancers that play a key role in the biological mechanisms of carcinogenesis; however, its role in cirrhosis progression to hepatocellular carcinoma is unknown.

  The investigators performed genome-wide DNA methylation profiling in pre-diagnostic samples from 22 cirrhosis patients who subsequently developed hepatocellular carcinoma and compared them to 22 cirrhosis patients who remained hepatocellular carcinoma-free during an average four-year follow-up. The researchers also examined a subset of patients without hepatitis C virus infection. The study identified three specific changes in DNA methylation that show a strong association with hepatocellular carcinoma risk. One change in the ADAM12 gene was associated with a lower risk of cancer, while two changes in the PSD3 gene showed a higher risk. These results held true even when the team excluded patients with hepatitis C from the analysis.

  The findings suggest that DNA methylation markers, derived from white blood cells in the blood sample, may identify biomarkers among cirrhosis patients at substantial risk for hepatocellular carcinoma before symptoms appear. Although researchers must conduct

further studies with a large patient cohort to validate these findings, the identification of predictive biomarkers suggests that healthcare providers will be able to stratify cirrhosis patients for risk-based treatment.

Baylor College of Medicine received a $3.6 million CPRIT Research Training grant (RP210037) for the Systems Epidemiology of Cancer Training Program, and three CPRIT Academic Research grants (RP150587, RP190641, RP220119) totaling $14.8 million for the Texas Hepatocellular Carcinoma Consortium.

Personnel

CPRIT has filled 53 full-time equivalent positions, including nine long-term contract employees.

CPRIT's 2024 Annual Report

As required by law, CPRIT submitted our annual report for fiscal year 2024 to the governor and the Texas legislature on January 31. The report, which CPRIT makes available exclusively online at http://annualreport.cprit.texas.gov highlights the progress CPRIT and our grantees have made in FY 2024 towards the agency's three-part mission to invest in the cancer research prowess of Texas' academic institutions, to create and grow the state's life science infrastructure, and to identify and fund innovation in the prevention, identification, treatment, and cures for cancer.

CPRIT's statute specifies several required components for the annual report, including:

- the grants approved during the fiscal year
- a summary of research findings reported in the fiscal year
- an assessment of CPRIT's grants and the overall strategy of the research program
- an economic estimate of how much cancer has cost the state
- the agency's compliance activities
- information related to reviewers' conflicts of interest

In addition to these required elements, we incorporate numerous grantee highlights and program features that illustrate the connection between the CPRIT grant projects and the advancements made in Texas' fight against cancer. In this year's report, we emphasized our grantees' work in cancer clinical trials, an essential component of CPRIT's mission.

While the report is a team effort across the entire agency, CPRIT's Communications Director Mark Loeffler, Digital Communications Specialist Justin Rand, technical writer Bridget Barstow, Information Resource Manager Shannon Cusick, and IT designer Royce Hart deserve special credit for the enormous amount of work necessary to put together the 2024 report.

89th Legislative Session Updates and Activities

The 89th Legislative Session convened in regular session at noon on January 14 and will adjourn *sine die* at midnight on June 2. The Texas Senate has three new members, and the Texas House has 31 new members.

Texas Senate

- The Texas Senate elected Sen. Brandon Creighton (R-Conroe) President Pro-Tempore, a largely ceremonial position that allows him to serve as lieutenant governor when Lt. Governor Dan Patrick is traveling out of state.

- Lt. Governor Patrick announced his standing committee assignments on January 17. As expected, Sen. Joan Huffman chairs the Senate Committee on Finance. Other members of Senate Finance are Sen. Chuy Hinojosa (Vice Chair), Sen. Carol Alvarado, Sen. Paul Bettencourt, Sen. Donna Campbell, Sen. Brandon Creighton, Sen. Pete Flores, Sen. Bob Hall, Sen. Lois Kolkhorst, Sen. Robert Nichols, Sen. Angela Paxton, Sen. Charles Perry, Sen. Charles Schwertner, Sen. Royce West, and Sen. Judith Zaffirini.

- Sen. Lois Kolkhorst chairs the Senate Committee on Health & Human Services. Other members of the Senate Health & Human Services Committee are Sen. Charles Perry (Vice Chair), Sen. César Blanco, Sen. Molly Cook, Sen. Bob Hall, Sen. Kelly Hancock, Sen. Bryan Hughes, Sen. Borris Miles, and Sen. Kevin Sparks.

Texas House of Representatives

- The House elected Rep. Dustin Burrows (R-Lubbock) Speaker of the House. He appointed former State Sen. Robert Duncan as Chief of Staff, with former TCEQ Commissioner Zak Covar serving as Deputy Chief of Staff, former State Rep. Tracy King serving as Senior Advisor, and Andrew Blifford continuing to serve as Director of Finance.

- The House passed a new set of rules (HR4) governing House operations. Changes adopted this session include a ban on minority party members serving as committee chairs, the abolishment of six standing committees, and a new standing committee – the Delivery of Government Efficiency Committee. Under the new rules, the membership of the House Committee on Public Health will increase from 11 members to 13 members and have a new subcommittee for Disease Prevention and Women's and Children's Health. Among other matters, the subcommittee will consider bills relating to preventing and treating cancer, including cancer screenings.

- I will update you when Speaker Burrows announces the House standing committee assignments, expected later this week.

Committee Hearings and Legislative Briefings

- Deputy Executive and Chief Operating Officer Heidi McConnell and I met with Sen. Sarah Eckhardt on January 8 to provide an update on CPRIT's activities.

- The Senate Committee on Finance held CPRIT's budget hearing January 29. I presented our budget request as outlined below in the section on General Appropriations Bills. Vice Presiding Officer Cindy Payne also provided invited testimony regarding CPRIT's exceptional item request. The committee had questions regarding CPRIT's return on investment, research accomplishments, revenue sharing, and the allocation of CPRIT's award portfolio to prevention grants. You can view the CPRIT's presentation here: https://senate.texas.gov/videoplayer.php?vid=21095&lang=en, beginning at 1:49 (one hour and 49 minutes into the video). Several advocates testified in support of CPRIT at the hearing. You can view their testimony beginning at 4:08 (four hours and 8 minutes into the video). We will follow up with the committee regarding requested items.

- Ms. McConnell and I will meet with Sen. Alvardo's staff on February 4 to provide an update on CPRIT's activities.

- I expect that the House Appropriations Committee will announce a committee hearing date for CPRIT's budget request shortly after the Speaker releases his committee assignments this week. I will notify you once we learn our hearing date; it may be as early as the week of February 10.

- We will continue to schedule meetings with state senators, state representatives, and their staff to update members on our activities.

General Appropriations Bills

- Texas Comptroller Glenn Hegar released the Biennial Revenue Estimate on January 13, which projects that the state will have $194.6 billion in revenue for general-purpose spending during the 2026-2027 biennium. This is the revenue amount that the legislature will work with during the budget drafting process. Comptroller Hegar asserted that the state is in good financial shape and that revenue collections will continue to increase in the upcoming biennium.

- The Texas Constitution mandates that the legislature must pass a budget bill each session. Both chambers filed their draft budget bills, Senate Bill 1 (SB1) and House Bill 1 (HB1) on January 22. The House and the Senate alternate every session serving as the lead body to develop the primary draft of the budget. This session, the Senate takes the lead, and a final version of SB1 will ultimately become law.

- Both chambers' budget bills provide CPRIT's full, constitutionally authorized annual appropriation of $300 million. In addition, both bills included CPRIT's requested additional

10 FTEs and removed the appropriations rider that transferred $3+ million per year to the Cancer Registry at the Texas Department of State Health Services. As a result, CPRIT has a single exceptional item request – increasing the Chief Executive Officer and Chief Scientific Officer exempt salaries by 10%.

- You will receive regular reports on legislative activities affecting CPRIT, including appropriations and general legislation.

Filed Legislation

As of January 31, legislators have filed 2,443 bills in the House and 1,092 bills in the Senate, for a total of 3,435 bills. Legislators will submit thousands more bills by the March 14 bill-filing deadline.

It appears that legislators have not filed any bills as of January 31 that directly affect CPRIT or CPRIT's enabling statute, Texas Health & Safety Code Chapter 102.

Other notable legislation includes:

- SB 124https://www.legis.texas.gov/BillLookup/History.aspx?LegSess=89R&Bill=SB124
  Sen. Bob Hall filed legislation relating to hospital patients' rights and hospital policies and procedures. The proposed legislation requires the hospital to adopt and implement a written policy ensuring a hospital patient's rights. Included in several enumerated rights proposed in the legislation is the right of a terminally ill patient to access and use certain investigational drugs, biological products, and devices that are in clinical trials in accordance with Texas' Right to Try Act (Texas Health & Safety Code Chapter 489).

- SB 209/HB 1268
  Sen. Royce West and Rep. Angie Chen Button filed legislation relating to the creation of the Texas Technology and Innovation Program within the Office of the Governor's Economic Development and Tourism Division. Under the proposed legislation, companies headquartered in Texas that qualify for and receive grants or contracts through the federal Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) programs would receive an additional State of Texas matching grant. With 345 Texas companies receiving SBIR/STTR funding in 2023, Texas ranks among the top ten states for attracting SBIR/STTR funding. However, according to the Texas Healthcare and Bioscience Institute, 34 states already have existing matching programs, and those states are using matching incentives to attract Texas companies to relocate.

- SB 998/SJR 47, HB 1302/HJR 90
  Dean Sen. Judith Zaffirini filed legislation to create the Alzheimer Prevention and Research Institute of Texas, modeled on CPRIT. This proposed bill is similar to CPRIT's enabling statute. Sen. Zaffirini also filed a senate joint resolution to amend the Texas Constitution establishing a special fund in the state treasury outside of the general revenue fund and authorizing the Texas Comptroller to transfer $3 billion from the general revenue fund to the

Alzheimer Prevention and Research Institute of Texas to serve as the source of funding for the agency's grants and operations. Rep. Richard Raymond filed companion legislation in the House.

- HB 185/HJR 24
  Rep. Senfronia Thompson filed legislation to establish the Mental Health and Brain Research Institute of Texas (MBRIT), modeled on CPRIT. This proposed bill is the same or similar to CPRIT's enabling statute and appears to be the same as the proposed legislation filed last session and passed by the House of Representatives. There is not a Senate bill companion filed at this time. Rep. Thompson also filed a house joint resolution to amend the Texas Constitution authorizing the Texas Comptroller to transfer $3 billion from the general revenue fund to the MBRIT fund. This transfer would serve as the source of funding for MBRIT's grants and operations.

- HB 975
  Representative Brian Harrison filed legislation relating to the "right to try" cutting-edge treatments, including individualized investigational treatments like cell and gene therapies, for patients with life-threatening or severely debilitating illnesses.

- HB 2298
  Rep. Suleman Lalani, M.D., filed legislation to create a health care facility grant program supporting the use of artificial intelligence technology in scanning medical images for cancer detection.

- SB 5 - Dementia Prevention and Research Institute of Texas (not yet filed)
  Lt. Governor Patrick announced his priority legislative items this session via a January 29 press release. The Lt. Governor reiterated his support for creating the Dementia Prevention and Research Institute of Texas (DPRIT), assigning the proposed legislation the low bill number SB 5, connoting its priority. The proposed budget bills filed by both chambers include $3 billion to fund DPRIT. Sen. Huffman will author SB 5; she has not filed it as of January 31.

CPRIT Outreach

Staff outreach activities during January include:

- At the invitation of former CPRIT CEO Wayne Roberts, I gave a wide-ranging presentation about CPRIT to the Westbank Historical Society on January 13.

- Kaliko Veiseh, Director of Financial Planning at Edelman Financial Engines, invited Senior Program Manager for Product Development Research Dr. Abria Magee to present an overview of CPRIT and its product development program on January 23 at the Bellaire/ Southwest Houston Rotary Club.

- I attended the first day of the Bootcamp Week for the fifth cohort of the Accelerator for Cancer Therapeutics (ACT) program at the Texas Medical Center (TMC) Innovation Factory in Houston on January 27. I gave a presentation about CPRIT, spoke with several prospective and current CPRIT grantees, and attended the welcome dinner.

- On January 28, Dr. Magee and I met with representatives from the University of Houston System, including Dr. Jonathan McCullers, Dean of Fertitta Family College of Medicine & Vice President of Health Affairs, Dr. Claudia Neuhauser, Vice President of Research, and Lindsay Lanagan, Associate Vice Chancellor of Government Relations, Health. We discussed CPRIT's programs and funding opportunities for the University of Houston System.

- Dr. Magee and I met with Dr. Allison Rhines, site head for JLABS@TMC, and Ashley Aguirre, JLABS@TMC Innovation Activation Manager, in Houston on January 28 to discuss the opportunity to co-host a future event in Houston for CPRIT-funded companies and interested investors.

- Dr. Magee and I met with Dr. Michelle Penn-Marshall, Vice President for Research and Innovation at Texas Southern University, on January 28 in Houston. She provided us with an update on the CPRIT-funded work that Texas Southern is doing to prevent cancer and accelerate cancer treatments.

- On January 28 I met with Steve Kean, President and CEO of the Greater Houston Partnership, in Houston to discuss collaboration opportunities for CPRIT and the Greater Houston Partnership.

- Chief Product Development Officer Dr. Ken Smith, Dr. Magee, and Program Manager for Product Development Dr. Michelle Leeuwon met with several representatives of the California Institute for Regenerative Medicine on January 29 to discuss CPRIT's experience and funding strategies for accelerating preclinical therapy development. Topics included portfolio prioritization, funding models for the path to IND, and award management.

- Dr. Magee attended an evening reception on January 30 hosted by Boulware & Valoir, an intellectual property law firm in Houston. The firm, listed in the Texas Resource Guide, collaborates with CPRIT-funded companies and applicants.

- On January 31, Oversight Committee member Tommy Taylor, Prevention Program Manager Carlton Allen, and former CPRIT CEO Wayne Roberts attended the American Cancer Society Cancer Action Network's "Cancer Research and Health Equity Breakfast" in Houston. CPRIT grantees, including Dr. Cliona Rooney, Baylor College of Medicine, and Dr. Upendra Marathi, 7 Hills Pharma, spoke on panels at the event.

- Throughout January, Dr. Magee and Dr. Leeuwon engaged with various companies, including Doloromics, Dr. Zhao of MD Anderson Cancer Center, Optheras, and Privo Technologies, to

discuss the upcoming April 2025 release of product development RFAs and the CPRIT Product Development application process and timeline.

Upcoming Events

There are upcoming events related to CPRIT, CPRIT grantees, or cancer that may be of interest to Oversight Committee members. Please contact me or the appropriate staff if you would like more information about an event or meeting.

Date	Event	Location
February 4 - 5	TAMEST 2025 Annual Conference: Transformational Breakthroughs	Irving
February 7	Consulate General of Denmark – webinar about oncology company opportunities in Texas *Dr. Magee will present*	Virtual
February 7	Geographic Diversity Advisory Committee	Virtual
February 10	Meeting with Rice University President Reginald DesRoches *CPRIT Senior Staff will attend*	CPRIT Office
February 10	Texas State University – Sponsors and Partners Panel *Dr. Moore will present*	San Marcos
February 20 - 21	Prevention Peer Review	Virtual
February 24	Advisory Committee on Childhood Cancer	Virtual
February 27	University Advisory Committee	Virtual

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of January 23, nine entities had not filed 18 academic research reports, and one product development report. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

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Onsite Reviews

CPRIT completed three onsite reviews in January. Onsite reviews are the most extensive monitoring activity conducted by CPRIT and include virtual or field visits led by compliance grant monitoring staff. CPRIT monitors the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and compliance with single audits during onsite reviews. Onsite monitoring enables CPRIT compliance staff to assess a grantee's capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists are collaborating with two grantees to address onsite review findings.

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Product development grantees, as well as those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed four annual match expenditure reviews in January. The total amount of match expenses reviewed by compliance staff for FY 2025 is $33,329,446.91. The unallowable match expenses for FY 2025 total $1,000. The reason for unallowable match expenses this fiscal year was that the company previously requested reimbursement for the expenses issue on a financial status report.

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In addition to the training webinar, all new product development grantees will receive FSR technical assistance training prior to the submission of their first FSR with expenses. This training is interactive with grantee staff, the assigned CPRIT grant accountant, and compliance staff participating. It will assist the grantee in preparing the required FSR, organizing support documentation, and in the correct use of the expense ledger template.

Academic Research Program Update

Recruitment FY 2025 Update

CPRIT's Application Receipt System (CARS) opened for the third cycle of FY2025 applications on October 22 and closed on November 20. The Scientific Review Council (SRC) reviewed these applications on December 12. Dr. LeBeau will present the recommended applications to the Oversight Committee in February 2025.

FY 25 Recruitment Cycle 3 Mechanism	Received	Requested
Recruitment of Established Investigators	1	$6,000,000
Recruitment of First-Time, Tenure Track Faculty Members	4	$6,500,000
TOTAL	**5**	**$12,500,000**

CARS opened for the fourth cycle of FY2025 applications on November 21, 2024, and closed on January 21, 2025. The SRC will review these applications on February 13. Dr Le Beau will present the recommended applications to the Oversight Committee in May 2025.

FY 25 Recruitment Cycle 4 Mechanism	Received	Requested
Recruitment of Established Investigators	2	$12,000,000
Recruitment of First-Time, Tenure Track Faculty Members	3	$6,000,000
TOTAL	**5**	**$18,000,000**

Academic Research FY 2025 Review Cycle 1 (25.1)

CPRIT posted the FY25.1 Request for Applications (RFAs) on February 22, 2024. CARS opened for applications on March 19, 2024, and closed on June 11, 2024. CPRIT conducted the Virtual Peer Review in October 2024. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in February.

FY 25 Cycle 1 Mechanism	Apps	Funds Requested
Individual Investigator Research Award (IIRA)	220	$196,400,895
IIRA for Computational Systems Biology of Cancer	29	$29,833,203
IIRA for Cancer in Children and Adolescents	36	$42,160,677
IIRA for Prevention and Early Detection	21	$24,022,601
IIRA for Clinical Translation	26	$41,025,711
IIRA for Early Onset Cancers	13	$11,379,861
Collaborative Action Program (competitive renewal)	1	$3,000,000
TOTAL	**346**	**$347,822,948**

Academic Research FY 2025 Review Cycle 2 (25.2)

CPRIT posted six FY25.2 RFAs on August 28, 2024. CPRIT's CARS opened for applications on September 18, 2024, and closed on December 10, 2024. FY25.2 RFAs included three RFAs for institutions eligible for the Texas Regional Excellence in Cancer (TREC) awards. The TREC awards include the reissue of a Pilot Project Award for early-stage projects, as well as two new TREC RFAs to provide support for Investigator-Initiated Research Awards and for Core Facility Support Awards to advance innovative research projects and to bring new state-of-the-art technologies to the institution's investigators. CPRIT will convene virtual peer review panels in March. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in May.

FY 25 Cycle 2 Mechanism	Apps	Funds Requested
Core Facility Support Awards (CFSA)	19	$52,693,483
High-Impact/High-Risk Research Awards (HIHR)	96	$23,987,428
Early Clinical Investigator Awards (ECI)	7	$6,888,2022
TREC: Core Facility Support Awards (TREC CFSA)	6	$11,980,341
TREC: Advancing Innovative Individual Research Awards at	18	$13,498,858

TREC-Eligible Institutions (TREC AIIRA)		
TREC Pilot Study Award (TREC PSA)	14	$2,755,701
TOTAL	160	**$111,804,013**

Academic Research FY 2026 Review Cycle 1 (26.1)

CPRIT posted six FY26.1 RFAs on January 14. CARS will open for applications on February 18 and close on May 6. The awards include the reissue of six Individual Investigator Research Awards. There are no new RFAs in this cycle. Peer review panels will meet in September. CPRIT's Chief Scientific Officer will present the SRC's recommendations to the PIC and Oversight Committee in November.

Product Development Research Program Update

Product Development FY 2025 Review Cycle 2 (25.2)

The Product Development Research team is working with GDIT to prepare and release the Competitive Cost Adjustment RFA that the Oversight Committee approved at its November 2024 meeting. Previously funded CPRIT companies that have substantially completed current contract goals and objectives and demonstrate a compelling justification for targeted CPRIT funds to expand their project and attract additional investment are eligible to apply. The process will be competitive, peer-reviewed, and will include a range of awards, none of which will be more than $3 million, or 30% of the original award budget, whatever is less. CPRIT plans to release these RFAs in February, with award recommendations presented for consideration at the May or August Oversight Committee meeting.

Prevention Program Update

Prevention FY 2025 Review Cycle 2 (25.2)

The prevention program released three RFAs on August 26, 2024, for the second review cycle of FY 2025. CPRIT received 21 applications by the deadline of December 5, 2024, deadline. Peer review will take place on February 20-21, 2025. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in May.

Cycle 25.2 Mechanism	Apps	Funds Requested
Primary Prevention of Cancer	8	$9.41 M
Cancer Screening and Early Detection	12	$22.02 M
Dissemination of CPRIT-Funded Cancer Control Interventions	1	$450,000
TOTAL	**21**	**$31.88 M**

Advisory Committees

- The Product Development Advisory Committee met on January 9.
- The Advisory Committee on Childhood Cancer met on January 27.
- The Clinical Trials Advisory Committee met on January 31.

Operations and Finance Update

Internal Audits

CPRIT accountant Michelle Huddleston is coordinating the agency's responses to document and information requests from Weaver & Tidwell, CPRIT's internal auditor, during the scoping and fieldwork phases of the agency's FY 2025 internal audit. The audit is reviewing agency expenditures spanning the period May 2023 to November 2024. Weaver selected a sample of 30 grant expenditures, totaling $3.9 million, and 70 non-grant expenditures, totaling $3.1 million, for testing.

Budget

The Texas legislature's 89th regular session formally convened on January 14 and the House and Senate each published its introduced version of the state's FY 2026-27 budget on January 22. Consistent with certain increases to the agency's base budget already incorporated in the introduced bills and at the LBB's direction, accountant Donna Cooper coordinated the effort to formally amend CPRIT's exceptional item request to each legislative chamber. CPRIT leadership presented an overview of its updated budget request to the Senate Finance Committee on January 29.

Finance

CPRIT initiated its second quarterly commercial paper issuance for FY 2025 in the amount of $69.5 million. The agency has confirmed receipt of the proceeds from the sale and will use the funds to support prevention ($6.5 million) and research ($63 million) grants awarded from FY 2019 through FY 2024.

Upcoming Subcommittee Meetings

I have listed below the subcommittee meetings that CPRIT will hold in advance of the February 19 Oversight Committee meeting. CPRIT staff will make the subcommittee agenda and meeting materials available in Govenda one week prior to each meeting.

Board Governance	February 6 at 10:00 a.m.
Audit	February 10 at 12:00 p.m.
Prevention	February 11 at 12:00 p.m.

Academic Research	February 12 at 12:00 p.m.
Product Development	February 13 at 10:00 a.m.

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CPRIT has awarded **2,038** grants totaling **$3.74 billion:**

- 311 prevention awards totaling $394.2 million
- 1,727 academic research and product development research awards totaling $3.35 billion

Of the $3.35 billion in academic research and product development research awards,

- 33.6% of the funding ($1.12 billion) supports clinical research projects.
- 22.8% of the funding ($762.1 million) supports translational research projects.
- 29.0% of funding ($971.4 million) supports recruitment awards.
- 11.9% of the funding ($397.2 million) supports discovery stage research projects.
- 2.7% of funding ($91.6 million) supports training programs.

CPRIT has 9 open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 6 Academic Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN P. DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	TEXAS HEALTH & SAFETY CODE SECTION 102.260(C) REPORT ON THE MERIT AND CONTINUED PROGRESS OF CPRIT'S PROGRAMS IN FISCAL YEAR 2024
DATE:	FEBRUARY 19, 2025

Summary

Texas Health and Safety Code § 102.260(c) requires the Chief Executive Officer to report to the Oversight Committee at least annually on the progress and continued merit of each research program. I am pleased to report that fiscal year 2024 marked another year of progress for CPRIT and its Academic Research, Prevention, and Product Development Research programs.

CPRIT approved 116 grants totaling $271.09 million to 28 organizations throughout the state in fiscal year 2024. Key metrics continue to indicate that CPRIT is affecting Texas' national standing in both cancer research and the biomedical industry. CPRIT's investment is attracting, creating, and expanding the research capabilities of our institutions of higher education and the state's life science industry, expediting innovation, and increasing the likelihood of breakthroughs in cancer prevention and cures.

This report illustrates the progress made in advancing CPRIT's mission to create and expedite innovation in cancer research and cancer prevention. Aligning program activities with the program priorities adopted by the Oversight Committee is a good gauge of progress and merit; this report highlights each program's implementation of the fiscal year 2024 program priorities. CPRIT's *2024 Annual Report*, which is available at https://2024annualreport.cprit.texas.gov/, provides more information on CPRIT program priorities and awards.

Regarding progress made by individual grant projects within each of CPRIT's three programs, Texas Administrative Code § 703.21 requires all CPRIT grantees to submit progress reports at least annually. Outside experts evaluate these progress reports to ensure that the grantee has made appropriate progress and should continue to work under the grant. If an expert reviewer determines that a grant project is not making progress towards the project goals and objectives, CPRIT has several options, including contract termination.

Milestones Across Programs

The Texas Academy of Medicine, Engineering, Science and Technology (TAMEST) awarded CPRIT the Kay Bailey Hutchinson Distinguished Service Award on February 5, 2024. The award recognizes individuals and organizations who have demonstrated outstanding leadership in furthering TAMEST's mission to bring together the state's brightest minds in medicine, engineering, science, and technology to foster collaboration and to advance research, innovation, and business in the State.

In December, CPRIT released the updated *2024 Texas Cancer Plan*, which is a statewide strategic plan to reduce the cancer burden across the state and improve the lives of Texans. The 2024 version is the third iteration of the Texas Cancer Plan published by CPRIT. The first and second versions were released in 2012 and 2018, respectively. The *2024 Texas Cancer Plan's* new immersive online format allows a comprehensive, adaptable approach to improving cancer prevention, care, and survivorship.

Academic Research Program

CPRIT's Academic Research Program supports innovative and meritorious projects that are discovering new information about cancer that can lead to prevention, early detection, and cures; translating new and existing discoveries into practical advances in cancer diagnosis and treatment; and increasing the prominence and stature of Texas in the fight against cancer. In fiscal year 2024, CPRIT's Oversight Committee approved 92 Academic Research and Recruitment Awards totaling $170.21 million.

Notably in 2024, the Academic Research Program launched the interactive Texas Core Facilities map, which is a comprehensive online resource that categorizes CPRIT-funded core facilities across the State. Core facilities offer their tools, technologies, and specialized competencies to researchers located throughout the State. The interactive map helps cancer researchers and companies more easily locate expertise, equipment, technologies, testing, and services applicable to their projects.

Academic Research Program Priorities

The Oversight Committee adopted the following fiscal year 2024 program priorities for the Academic Research Program:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate adoption and deployment of evidence-based prevention, early detection, risk assessment and interventions
- Computational oncology and analytic methods
- Childhood and adolescent cancers

- Hepatocellular cancer
- Expand access to innovative clinical trials

The *2024 Annual Report* highlights the work of Dr. Michael Taylor at Baylor College of Medicine in exemplifying program priorities in practice. Dr. Taylor arrived at Baylor College of Medicine with the support of a CPRIT Recruitment of Established Investigators grant award in 2022. He and his team research novel treatments for pediatric brain tumors, including Group 3 medulloblastoma. Dr. Taylor's research team identified embryonic cells responsible for the tumor and showed in preclinical models that removing these stem-like cells caused tumors to shrink. While scientists will need to conduct more research, this discovery provides hope for earlier treatment. From this research, Dr. Taylor hopes to create a biomarker test for newborns that will detect early signs of medulloblastoma.

Prevention Program

CPRIT's Prevention Program continues to support effective, evidence-based prevention programs available to underserved populations in the state. Prevention Program grants help Texans reduce the risk of cancer, identify cancers earlier, and assist people in finding cancer treatment. As of August 31, 2024, prevention grants had provided 9.89 million prevention services, including 3.8 million clinical services. Through CPRIT-funded screenings, 44,751 cancers and cancer precursors have been discovered. In fiscal year 2024, the Oversight Committee approved 12 prevention grants totaling $25.9 million.

Prevention Program Priorities

The Oversight Committee adopted the following fiscal year 2024 Prevention Program priorities:

- Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services
- Program assessment to identify best practices, use as a quality improvement tool, and guide future program direction.

The Southwest Coalition for Colorectal Cancer Screening (SuCCCeS) program, led by Jennifer Molokwu at Texas Tech University Health Sciences Center El Paso and funded by CPRIT, is improving screening rates for colorectal cancer among uninsured and underinsured 45- to 75-year-olds. The incidence and mortality rates of colorectal cancer are higher in El Paso County than in the rest of the State. The SuCCCeS program focuses on sustainably engaging health care systems and community organizations to reduce colorectal cancer disparities through evidence-based educational intervention, navigation services, and no-cost screening and diagnostic testing. Serving a 27-county area, the program is available to 2.56 million medically underserved

Texans. To date, SuCCCeS has distributed over 31,000 fecal immunochemical test (FIT) kits, with a completion rate of 71%. Based on FIT test results, doctors scheduled almost 500 screening colonoscopies, with a 78% completion rate.

Product Development Research Program

CPRIT's Product Development Research Program funds innovative and scientifically meritorious product development projects with the potential of translating research discoveries into commercial products to benefit cancer patients. During fiscal year 2024, the Oversight Committee approved 12 Product Development Research awards totaling $74.97 million. Through August 31, 2024, CPRIT has cumulatively approved 80 product development research awards to 67 companies totaling a commitment of $714.2 million.

The Product Development Research program continues to be a vital component in building the life sciences infrastructure and community in Texas. Through August 31, 2024, CPRIT companies raised $7.1 billion in additional investments after their CPRIT awards (a 10:1 funding ratio). These additional investments and activities testify to the quality of the CPRIT-funded projects and CPRIT's review process. CPRIT-funded companies continue to help not only the life sciences ecosystem, but also the Texas economy with a $672.2 million increase in business activity in CPRIT programs and employment of 1,866 Texans at CPRIT-funded companies.

In fiscal year 2024, the Product Development program received a record number of grant applications. For preliminary review, companies submitted 142 applications, with 31 companies invited to submit full applications. Ultimately, CPRIT approved 12 of those 31 companies for grant awards. The high volume of companies applying for CPRIT funds is a testament to the growing life sciences industry in Texas and the role that CPRIT plays to help foster it.

Product Development Research Program Priorities

The Oversight Committee adopted the following 2023 Product Development Research Program Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits, i.e., disruptive technologies
- Funding projects addressing large or challenging unmet medical needs
- Investing in early-stage projects when private capital is least available
- Stimulating commercialization of technologies developed at Texas research entities
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially C-level executives
- Providing appropriate return on Texas taxpayer investment

CPRIT grantee Prana Surgical (formerly Prana Thoracic) is developing a novel device to improve lung cancer detection and treatment. In 2022, Prana Surgical received a Seed Company Product Development Research grant to develop the Minimally-invasive Targeted Resection

(MiTR-core™), a device that safely removes lung nodules through a minimally invasive procedure. With the support of the CPRIT grant, Prana was able to accelerate the development of the MiTR-core™ through clinical and regulatory requirements. Due to the successfully broader application beyond lung tissue, MiTR-core™ is now the "Prana System."

Conclusion

Fiscal Year 2024 was another successful year for CPRIT's three programs, all of which show merit and progress and should continue operations. The work conducted under the purview of CPRIT's programs is part of an iterative cycle, with observations emerging from the laboratory making their way to the public and back again to the laboratory. Essential players in this cycle are basic scientists, physician scientists, clinical researchers, product development entrepreneurs, public health professionals, health care providers, patients, community organizations, early-stage companies, and research institutions across Texas.

Through CPRIT's programs, the state is investing in intellectual and research support infrastructure that is attracting, creating, and expanding research capabilities of Texas institutions of higher education and the Texas life science industry; expediting innovation; and increasing the likelihood of breakthroughs in cancer prevention and cures.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	FEBRUARY 11, 2025

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities and assuring the Oversight Committee that controls are in place to prevent, detect, and mitigate compliance risk. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies. In addition, the Compliance Officer is responsible for monitoring the timely submission status of required grant recipient reports and notifying the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT has approximately $1.5 billion in grants under management, with 540+ grants that are either active or wrapping up grant activities. We receive an average of 540 grantee reports each month. As of January 31, nine entities had not filed 18 academic research reports and one product development report. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MICHELLE LE BEAU, PH.D., CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH PROGRAM UPDATE
DATE:	FEBRUARY 19, 2024

Topics in this memo address updates on special projects, the opening of the Fiscal Year (FY) 2026 Cycle 1 RFAs, closing of the FY 2025 Cycle 2 RFAs and Recruitment Cycle 4, and Advisory Committee meetings.

Special Projects Updates

- Reducing the timeline from application submission to potential award from 12 months to 7 months, a goal set for FY 2025, was met with the FY 2025 Cycle 2 and FY 2026 RFAs. Besides evident efficiencies, this timeline provides an improved spread of recommended applications presented to the Oversight Committee quarterly, especially the fourth quarter. Numerous institutions and principal investigators have enthusiastically applauded this change. This timeline will be carried forward in future fiscal years.
- The CPRIT-Funded Core Facilities Interactive Map now includes newly funded core facilities and the retirement of closed core facilities. According to feedback, the CPRIT Interactive Core Facility Map is a popular CPRIT tool for Texas cancer researchers.
- Expansion of the Clinical Trials Advisory Committee (CTAC) membership, a goal presented by CTAC Chair Dr. David Gerber in his 2024 Annual Report to the Oversight Committee, is making great strides with the successful recruitment of three new members representing clinical trialists from the Rio Grande Valley, Texas Oncology, and a safety net hospital.

Open RFAs: Fiscal Year 2026 Cycle 1 (FY26.1) RFAs

CPRIT posted the following FY26.1 RFAs on January 14, 2025. CPRIT's Application Receipt System (CARS) will open for applications on February 18, 2025, and will close on May 6, 2025. The awards include the reissue of six Individual Investigator Research Awards. No new RFAs are included in this cycle. Virtual peer review will be conducted in September 2025. CPRIT's Chief Scientific Officer will present the Scientific Reviews Council's recommendation to the PIC and Oversight Committee in November 2025.

Individual Investigator Research Awards
Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations.
Award: Up to $300,000 per year. Maximum duration: 3 years.

Individual Investigator Research Awards for Computational Systems Biology of Cancer
Supports applications for innovative mathematical and/or computational research projects addressing questions that will advance current knowledge in the (a) mechanisms that tie altered gene expression and downstream molecular mechanisms to functional cancer phenotypes and/or (b) mechanisms that tie tumor morphology to functional cancer phenotypes and/or mechanisms that tie treatment sequence and combination to evolving functional cancer phenotypes (that emerge as a result of treatment selection).
Award: Up to $350,000 in total costs per year for up to 3 years.

Individual Investigator Research Awards for Cancer in Children and Adolescents
Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near- or long-term.
Award: Up to $300,000 per year. Maximum duration: 4 years.

Individual Investigator Research Awards for Prevention and Early Detection
Supports applications which propose clinical and population-based projects designed to develop effective prevention and early detection interventions to reduce cancer risk, mortality, and morbidity among Texans. Projects that propose such research collaborations with existing CPRIT Prevention Program awardees including the CPRIT funded *Texas Collaborative Center for Hepatocellular Cancer* (https://www.bcm.edu/research/labs-and-centers/research-centers/texas-collaborative-center-for-hepatocellular-cancer) and cancer survivorship research to enhance the health and well-being of all cancer survivors and caregivers, are strongly encouraged.
Award: Up to $300,000 per year. Maximum duration: 4 years.

Individual Investigator Research Awards for Clinical Trials
Supports applications that propose innovative cancer clinical studies in adults or children and adolescents that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices. Clinical trial must be planned to begin when the contract is awarded.
Award: Up to $400,000 per year. Maximum duration: 4 years.

Individual Investigator Research Awards for Early-Onset Cancers
Supports innovative research projects that will significantly advance the knowledge of etiology, prevention, cancer biology, and treatment of early-onset cancers.

Award: Up to $300,000 per year for a 3-year period

Closed RFAs: Fiscal Year 2025 Cycle 2 (FY25.2) RFAs

The following FY25.2 RFAs were posted on August 28, 2024. CPRIT's Application Receipt System (CARS) opened for applications on September 18, 2024, and closed on December 10, 2024. FY25.2 RFAs included three RFAs for institutions eligible for the Texas Regional Excellence in Cancer (TREC) awards designed for institutions with a growing cancer research funding base. The TREC awards include the reissue of a Pilot Project Award for early-stage projects, as well as two new TREC RFAs to provide support for Investigator Initiated Research Awards and for Core Facility Support Awards to advance innovative research projects and to bring new state-of-the-art technologies to the institution's investigators. Virtual Peer Review will be conducted in March 2025. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in May 2025.

Core Facility Support Awards
Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. Funds may be requested to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions.
Award: The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of $3,000,000 in total costs.

High-Impact/High-Risk Research Awards
Supports applications that explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. The HIHR Research Awards are expected to provide the foundation for individual or multiple investigator peer-reviewed awards upon completion. The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data.
Award: Applicants may request a total of $250,000 for a period of up to 24 months.

Early Clinical Investigator Awards
Solicits applications from institutions to provide cancer physicians early in their academic career the opportunity to develop clinical research skills and to gain experience in advanced methods and experimental approaches needed to become clinical investigators; to provide an opportunity to establish a partnership with a laboratory-based collaborator in order to design and conduct correlative studies needed to interpret the outcome of an interventional trial; to provide the protected time from clinical responsibilities required to develop and conduct investigator initiated clinical trials; and to increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, capitalizing on basic discoveries and

translating them through conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.
Award: Up to $1,000,000 (total costs) Maximum duration: 5 years

TREC: Core Facility Support Awards
Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects at TREC-eligible institutions. Funds may be requested to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions.
Award: The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of $2,000,000 in total costs.

TREC: Advancing Innovative Individual Research Awards at TREC-Eligible Institutions
Supports research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. This award allows experienced or early-career-stage cancer researchers the opportunity to explore new methods and approaches for investigating a question of importance that has been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.
Award: Applicants may request up to a maximum of $750,000 in total costs over 3 years.

TREC Pilot Study Award
Provides short-term funding to explore the feasibility of cancer research projects at TREC-eligible institutions that, if successful, would contribute new insights into the etiology, diagnosis, treatment, or prevention of cancers forming the basis for applications for peer-reviewed funding from CPRIT or other organizations.
Award: Total of $200,000 over a period of 2 years.

Table 1: Application Submission data for FY2025 Cycle 2

Mechanism	Submitted	Total Funding Requested
Core Facility Support Awards	19	$52,693,483
High-Impact/High-Risk Research Awards	96	$23,987,428
Early Clinical Investigator Awards	7	$6,888,2022
TREC: Core Facility Support Awards	6	$11,980,341
TREC: Advancing Innovative Individual Research Awards at TREC-Eligible Institutions	18	$13,498,858
TREC Pilot Study Award	14	$2,755,701
Total	**160**	**$111,804,013**

FY2025 Recruitment Update

CPRIT's Application Receipt System (CARS) opened for the fourth cycle of FY2025 applications on November 21, 2024, and will close on January 21, 2025. The Scientific Review Council will review these applications on February 13, 2025, and recommended applications will be presented to the Oversight Committee in May 2025.

Table 2: Recruitment Application Submission data for Cycle 25.4

Mechanism	Applications Received	Funds Requested
Recruitment of Established Investigators	2	$12,000,000
Recruitment of Rising Stars	0	$0
Recruitment of First-Time, Tenure Track Faculty Members	3	$6,000,000
TOTAL	**5**	**$18,000,000**

CPRIT's Application Receipt System (CARS) opened for the second cycle of FY2025 on August 21, 2024, and closed on October 21, 2024. FY2025 Cycle 3 opened on October 22, 2024, and closed on November 20, 2024. The Scientific Review Council reviewed these applications on November 14, 2024 (Cycle 1) and December 12, 2024 (Cycle 2) and recommended applications will be presented to the Oversight Committee in February 2025.

Table 3: Recruitment Application Submission data for Cycles 25.2 and 25.3

Mechanism	Applications Received	Funds Requested	Applications Recommended	Funds Requested
Recruitment of Established Investigators	2	$12,000,000	1	$6,000,000
Recruitment of Rising Stars	4	$16,000,000	0	$0
Recruitment of First-Time, Tenure Track Faculty Members	6	$10,500,000	5	$10,000,000
TOTAL	**12**	**$38,500,000**	**6**	**$16,000,000**

Advisory Committees Meetings

- The Childhood and Adolescent Cancer Advisory Committee met on January 26, 2025.
- The Clinical Trials Advisory Committee met on January 31, 2025.
- The Geographic Diversity Advisory Committee met on February 7, 2025.
- The University Advisory Committee is meeting on February 27, 2025.

Table 4: Scheduled Advisory Committees Annual Report Presentations

OC Meeting	Presenting Advisory Committee(s)
November	Prevention Advisory Committee, Geographic Diversity Advisory Committee
February	Advisory Committee on Childhood and Adolescent Cancers
May	University Advisory Committee
August	Clinical Trials Advisory Committee, Product Development Advisory Committee

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: FEBRUARY 11, 2025

FY 2025 Review Cycle 2 (25.2)

The Prevention Program released three RFAs, *Primary Prevention of Cancer, Cancer Screening and Early Detection*, and *Dissemination of CPRIT-Funded Cancer Control* Interventions, on September 26, 2024, for the second cycle of FY 2025. CPRIT received 21 proposals totaling $37,048,970 by the December 5, 2024, deadline. Peer review will take place on February 20-21, 2025, and the Prevention Review Council (PRC) will meet in April 2025, to make recommendations to the Program Integration Committee (PIC). Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in May 2025.

Mechanism	Apps Received	Funds Requested
Cancer Screening and Early Detection	12	$22,024,104
Primary Prevention of Cancer	8	$ 9,410,405
Dissemination of CPRIT-Funded Cancer Control Interventions	1	$ 450,000
TOTAL	**21**	**$31,884,509**

FY 2026 Review Cycle 1 (26.1)

The Prevention Program will release three RFAs, *Primary Prevention of Cancer, Cancer Screening and Early Detection*, and *Dissemination of CPRIT-Funded Cancer Control Interventions*, on March 19, 2025, for the first cycle of FY 2026. Peer review will take place August – September 2025, and the PRC will meet in October 2025, to make recommendations to the PIC. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in November 2025.

Resources

The American Cancer Society recently released Cancer Facts and Figures 2025.
Cancer Facts & Figures 2025 is an educational companion for Cancer Statistics 2025, a scientific paper published in the American Cancer Society journal, *CA: A Cancer Journal for Clinicians*. These annual reports provide:

- Estimated numbers of new cancer cases and deaths in 2025 by cancer site and US state
- Current cancer incidence, mortality, and survival statistics
- Information on cancer symptoms, risk factors, early detection, and treatment

Other Activities

Carlton Allen, Program Manager for Prevention, had an opportunity to travel to Houston on January 30-31. He met with Dr. Ajewole and other Texas Southern University (TSU) leadership and staff. He toured the TSU campus and saw the GCC Center for Comprehensive PK/PD & Formulation, a CPRIT-funded core facility.

Mr. Allen also attended the 2025 American Cancer Society Cancer Action Network (ACS CAN) Houston Research and Health Equity Breakfast. This event convened leaders from across Texas to discuss accelerating research, reducing cancer disparities, and improving health equity in Texas.

Program staff assisted with the 2024 Annual Report and edited and updated the 3 Cycle 26.1 Prevention RFAs.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KEN SMITH, PH.D., CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT: PRODUCT DEVELOPMENT PROGRAM UPDATE
DATE: FEBRUARY 19, 2025

Product Development FY 2025 Review Cycle 2 (25.2)

This month, we will release the Supplemental Awards for Product Development Research request for applications (RFA) that the Oversight Committee approved at its November 2024 meeting. The total funding remaining from FY 2025 for this RFA is $10,311,921. This RFA will allow previously funded CPRIT companies that have substantially completed current contract goals and objectives and demonstrate a compelling justification for targeted CPRIT funds to expand their project and attract additional investment. The process will be competitive, peer-reviewed, and will include a range of awards, some of which may be less than one million dollars and up to three million dollars. Those grantees awarded before the FY 2024 Cycle 2 are eligible to apply. I will present award recommendations for consideration at the May 21, 2025, Oversight Committee meeting.

Product Development FY 2025 Review Cycle 1 (25.1) Overview

In early July 2024, CPRIT issued 24 invitations to submit FY 2025 Product Development Research full applications to companies receiving the best preliminary application scores. Of the 24 invitations, 22 companies submitted their full applications to CPRIT by the July 25 deadline. These companies presented their proposals to the individual review panels in September 2024. Based upon the application scores and presentations to the panels, nine companies were recommended and approved by the Oversight Committee in November 2024. The total funding awarded for the 25.1 cycle was $63,566,376.

CPRIT Resource Guide

Product Development program staff receives multiple requests to add new entries each week and works with the CPRIT communications team to issue regular updates.

Product Development Advisory Committee (PDAC)

The PDAC met on January 9 to discuss CPRIT's product development program, including the FY 2025 review cycles and the current state of biotech funding.

FY 2026 Requests for Applications
I recommend that the Oversight Committee approve the proposed FY 2026 Product Development requests for applications (RFAs):

- Texas Therapeutic Company Award (TTC)
- Texas Device and Diagnostics Company Award (TDDC)
- Texas New Technologies Company Award (TNTC)
- Texas Seed Company Award (SEED)

The FY 2026 RFAs will be the same as the those released for the FY 2025 review cycles, with updated information as appropriate. We plan to release these RFAs in late April/early May and open the portal for preliminary applications. The first full application deadline will be sometime in June/July, with award announcements planned for the November 2025 Oversight Committee meeting.

February 2025 Oversight Committee
Internal Audit Status Report
February 10, 2025

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Daniel Graves, Partner.

2025 Internal Audit Plan and Schedule

Based on the approval of the 2025 Internal Audit Plan by the Oversight Committee in the August 2024 meeting, we have coordinated and planned the timing of the internal audits and follow-up procedures for the 2025 Internal Audit Plan.

2025 INTERNAL AUDITS		
Internal Audit	**Description**	**Status**
Post-Award Grant Monitoring	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Post-Award Grant Monitoring processes. Activities to be evaluated include the processes for the review of financial statement reports and reimbursement of funds to grant recipients.	**Fieldwork In Progress Started January 13**
Procurement and P-Cards Advisory	Internal Advisory Audit will include an evaluation of risks and internal controls in place related to CPRIT's P-Card processes. Activities to be evaluated include the processes for use of CPRIT's p-cards and the utilization of the state's p-card rebates.	**Planning In Progress Scheduled to Start February 24**
Non-Grant Expenditures	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's non-grant expenditure processes. Activities to be evaluated include the review of invoices, vendor payments, vendor monitoring. and the cancellation of warrants in the CAPPS system.	**Fieldwork In Progress Started January 13**

2025 INTERNAL AUDIT FOLLOW-UPS		
Communications Follow-Up	Internal Audit will perform follow-up procedures to validate remediation of the one high risk finding that is partially remediated.	**Fieldwork Scheduled for June**
IT General Controls Follow-Up	Internal Audit will perform follow-up procedures to validate the remediation of the one finding remaining open, which substantial progress was made towards remediation.	**Fieldwork Scheduled for April**

We have prepared a summary schedule of audits, their status and a summary of the findings by risk rating. The schedule maps out the internal audit and follow-up procedures performed, by year, the report date, report rating, and the findings by risk rating. The summary schedule is attached.

During the August Oversight Committee meeting the fiscal year 2025 Internal Audit Plan and Annual Report were approved. In compliance with the Texas Internal Audit Act, these documents were submitted to the SAO, Governor's Office and the LBB before November 1, 2024.

Daniel Graves, CPA, Internal Auditor
Partner
Weaver and Tidwell L.L.P.

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of February 10, 2025

					Open Findings				Closed Findings				Total Findings			
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**
Fiscal Year 2017																
2016 Information Security Follow-Up	2017	Complete	May 30, 2017													
Fiscal Year 2017 Subtotal					**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Fiscal Year 2018																
Communications Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	-	5
2016 Information Security Follow-Up	2018	Complete	July 17, 2018													
Fiscal Year 2018 Subtotal					**1**	**4**	**-**	**5**	**-**	**-**	**-**	**-**	**1**	**4**	**-**	**5**
Fiscal Year 2019																
2016 Information Security Follow-Up	2019	Cancelled	N/A													
2018 Communications Follow-Up	2019	Complete	August 30, 2019	Satisfactory	1	4	-	5	-	2	-	2	1	2	-	3
Fiscal Year 2019 Subtotal					**1**	**4**	**-**	**5**	**-**	**2**	**-**	**2**	**1**	**2**	**-**	**3**
Fiscal Year 2020																
Governance	2020	Complete	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1
2016 Information Security Follow-Up	2020	Complete	N/A													
2018 Communications Follow-Up	2020	Complete	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3
Fiscal Year 2020 Subtotal					**1**	**5**	**-**	**6**	**-**	**2**	**-**	**2**	**1**	**3**	**-**	**4**
Fiscal Year 2021																
Sunset Self-Assessment Advisory	2021	Cancelled	N/A	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Information Technology General Computer Controls	2021	Complete	September 24, 2022													
Grantee Compliance Records Management	2021	Rescheduled	FY 2022	N/A	-	-	-	-	-	-	-	-	-	-	-	-
2016 Information Security Follow-Up	2021	Rescheduled	FY 2022													
2018 Communications Follow-Up	2021	Rescheduled	FY 2022	N/A	1	4	-	5	-	2	-	2	1	2	-	3
2020 Governance Follow-up	2021	Rescheduled	FY 2022	Strong	-	1	-	1	-	-	-	-	-	-	-	1
2020 Disaster Recovery and Business Continuity Follow-up	2021	Complete	September 28, 2021	N/A	-	-	-	30	-	-	-	25	-	-	-	5
Fiscal Year 2021 Subtotal					**1**	**5**	**-**	**36**	**-**	**2**	**-**	**27**	**1**	**2**	**-**	**9**
Fiscal Year 2022																
Vendor Contract Compliance	2022	Complete	October 25, 2022	Strong	-	-	2	2	-	-	-	-	-	-	2	2
Information Technology General Computer Controls	2022	Cancelled	N/A													
2016 Information Security Follow-Up	2022	Cancelled	N/A													
2018 Communications Follow-Up	2022	Complete	October 28, 2022	Satisfactory	1	4	-	5	-	4	-	4	1	-	-	1
2020 Governance Follow-up	2022	Complete	October 28, 2022	Strong	-	1	-	1		1	-	1	-	-	-	-
2020 Disaster Recovery and Business Continuity Follow-up	2022	Complete	October 28, 2022														Note 1
Fiscal Year 2022 Subtotal					**1**	**5**	**2**	**8**	**-**	**5**	**-**	**5**	**1**	**-**	**2**	**3**

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of February 10, 2025

Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Open Findings				Closed Findings				Total Findings				
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total	
Fiscal Year 2023																	
Contract Risk Assessment	2023	Complete	May 1, 2023	N/A	-	-	-	1	-	-	-	-	-	-	-	1	**Note 2**
Post-Award Grant Compliance Program	2023	Complete	September 12, 2023	N/A	-	-	-	-	-	-	-	-	-	-	-	-	
Purchasing Compliance	2023	Complete	September 22, 2023	Strong	-	-	1	1	-	-	-	-	-	-	1	1	
IT General Controls	2023	Complete	September 18, 2023	Satisfactory	1	4	3	8	-	-	-	-	1	4	3	8	
2016 Information Security Follow-Up	2023	Cancelled	N/A														
2018 Communications Follow-Up	2023	Complete	October 27, 2023	N/A	2	4	-	6	1	4	-	5	1	-	-	1	
2020 Disaster Recovery and Business Continuity Follow-up	2023	Complete	July 31, 2023														
2022 Vendor Contract Compliance Follow-up	2023	Complete	October 27, 2023	Strong	-	-	1	1	-	-	1	1	-		-	-	
Fiscal Year 2023 Subtotal					**3**	**8**	**5**	**17**	**1**	**4**	**1**	**6**	**2**	**4**	**4**	**11**	
Fiscal Year 2024																	
Internal Agency Compliance	2024	Complete	April 5, 2024	Strong	-	-	-	-	-	-	-	-	-	-	-	-	
Records Management Advisory	2024	Complete	August 1, 2024	N/A	-	-	-	-	-	-	-	-	-	-	-	-	
Oversight Committee Reporting	2024	Complete	August 1, 2024	Strong	-	-	-	-	-	-	-	-	-	-	-	-	
2023 Purchasing Compliance Follow-up	2024	Complete	April 12, 2024	Strong	-	-	1	1	-	-	1	1	-	-	-	-	
2018 Communications Follow-Up	2024	Complete	August 1, 2024	N/A	1	4	-	5	-	4	-	4	1	-	-	1	
2023 IT General Controls Follow-up	2024	Complete	August 1, 2024														
Fiscal Year 2024 Subtotal					**1**	**4**	**1**	**6**	**-**	**4**	**1**	**5**	**1**	**-**	**-**	**1**	

Open Items Summary																	
Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Findings				Closed Findings				Total Open Findings				IA Follow-Up Procedure Timing
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total	
2018 Communications Follow-Up	2024	Complete	August 1, 2024	N/A	1	4	-	5	-	4	-	4	1	-	-	1	**FY 2025**
2023 IT General Controls Follow-up	2024	Complete	August 1, 2024														**FY 2025**
Total Findings For Internal Audit Follow-Up					**1**	**4**	**-**	**5**	**-**	**4**	**-**	**4**	**1**	**-**	**-**	**1**	

NOTE 1: The 2020 Disaster Recovery and Business Continuity findings are recommendations for improvement of the DR/BCP documentation. Therefore, they do not have a risk rating associated with them.

NOTE 2: The 2023 Contract Risk Assessment finding is a recommendation for implementing a Contract Risk Assessment required by state contract monitoring requirements. Therefore, they do not have a risk rating associated with them.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	FEBRUARY 11, 2025

Summary and Recommendation

I have appointed six experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their February 6 meeting, the Board Governance subcommittee reviewed the appointees to the Academic Research and Product Development Research peer review panels and voted to recommend that the Oversight Committee approve the six appointments.

Discussion

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform a significant role for the state; a Scientific Research and Prevention Programs committee must first recommend any CPRIT grant award before the Oversight Committee may consider the proposed award. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Board Governance Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The Board Governance Subcommittee reviewed the six appointees at its February 6 meeting and recommends their approval by the Oversight Committee.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Scientific Research and Prevention Program Committee ("Peer Reviewer") Appointments
February 2025

Program/ Panel	Name	Organization	Title	Expertise
Academic Research (Basic Cancer Research 2 panel)	Joseph Costello, Ph.D.	Department Neurological Surgery University of California San Francisco Boston, MA San Francisco, CA	Professor	Epigenetics, DNA Sequencing, DNA Methylation, Molecular and Computational Biology, Genetic Mutations, Gene Expression, Longitudinal Genomics, MRI-Guided Tumor Biopsies, Brain Tumors, Glioma, Brain Tumor Genomics, TERT, Cellular Immortality
Prevention	Sherrie Wallington, Ph.D.	George Washington University School of Nursing	Associate Professor (Tenured)	cancer prevention, cancer disparities, health communication, and health literacy utilizing mixed methods and community-based participatory research
Product Development Research	Pamela Carroll, Ph.D.	Isomorphic Labs	Chief Operating Officer	AI, drug development, immunology, oncology, cell and development biology
Product Development Research	Joseph A. Leveque, M.D.	MEDIKINE	President and CEO	Oncology, immunology, and neurology, clinical development, regulatory affairs, pharmacovigilance, finance
Product Development Research	Lucy Liu, Ph.D.	Longwood Fund	Principal	Neuron development and metabolism, venture capital investment, biotech startup strategy, fundraising

Program/ Panel	Name	Organization	Title	Expertise
Product Development Research	Uciane K. Scarlett, Ph.D.	Stealth	Investor	Investment, oncology, gene therapy, immunology
Product Development Research	Adrian Woolfson, Ph.D.	Replay Holdings, INC	Founder, Executive Chairman, and President	Gene and cell therapy, synthetic biology, virology, oncology, immuno-oncology

Academic Research nominations for Peer Reviewers

Nominees	Panel Assignment	Expertise
Joseph Costello, PhD Professor Department Neurological Surgery University of California San Francisco Boston, MA San Francisco, CA	**BCR-2**	Epigenetics, DNA Sequencing, DNA Methylation, Molecular and Computational Biology, Genetic Mutations, Gene Expression, Longitudinal Genomics, MRI-Guided Tumor Biopsies, Brain Tumors, Glioma, Brain Tumor Genomics, TERT, Cellular Immortality

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Costello, Joseph F.

eRA COMMONS USER NAME (credential, e.g., agency login): JCOSTELLO

POSITION TITLE: Professor, Karen Osney Brownstein Endowed Chair, Neurosurgery

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Marquette University	B.S.	06/1988	Biology
Loyola University Graduate School, Chicago, IL	Ph.D.	12/1994	Neuroscience
Ludwig Institute for Cancer Research, San Diego	Postdoctoral	12/1999	Cancer

A. Personal Statement

I am a Professor of Neurosurgery at UCSF and hold the Karen Osney Brownstein Endowed Chair in Neuro-oncology. I am serving as the Director of the NIH-supported Training Program in Translational Brain Tumor Research at UCSF. From September 2018 - 2023, I served as the overall PI of Basic Science for the UCSF Brain Tumor SPORE program and was a member of the SPORE Executive Committee, and from 2023-2028 I was the Director of the SPORE Career Development and Developmental Research Programs. I am an Executive Committee member of the BMS graduate program at UCSF and a lecturer for an Internal Advisory Board member of the Office of Education in the Helen Diller Cancer Center, which serves career development and educational aspects of pre and postdoctoral fellows in cancer research. Examples of his mentoring activities include serving as mentor/co-mentor for high school, undergraduate, and medical student trainees, trainees at the PhD and postdoc level funded through F31, F99/K00, T32, and F32 from NIH, and junior faculty who have received K08, K12, K23, and R01 awards. The Costello laboratory is composed of cell, molecular, and computational biologists working alongside clinician-scientists. Our goal is to understand the full evolutionary history of human brain tumors, from immortality through intra-tumoral heterogeneity and tumor recurrence. We use a variety of genomic and epigenomic methods. Tumor cell immortality involves TERT activation through mutation in the TERT promoter. TERT promoter mutation is the third most common mutation in human cancer and the most frequent mutation in several CNS cancers, including GBM. Together with the Song laboratory, we discovered that the multimeric factor, GABP is recruited by the mutation to activate TERT and immortalize brain cells, allowing them to proliferate indefinitely and evolve into tumors. In collaboration with the Doudna lab, we identified additional features of the GABP recruitment in glioma (Mancini, Cancer Cell, 2018), including rare, recurrent duplications in the TERT promoter (Barger, Nature Communications, 2022). We recently reported on the cellular and genetic roots of glioblastoma from a whole tumor perspective (Mathur, et al. *Cell*).

Ongoing and recently completed projects that I would like to highlight include:

R01CA244838
Costello (PI)
07/01/2020–06/30/2025
NIH/NCI
3-D spatial approach to discover genomic effectors of immunosuppression during malignant transformation

P50CA097257

Berger (PI). Role: Director of CEP and DRP programs
09/01/2023-08/31/2028
NIH/NCI
Brain Tumor SPORE Grant

P01CA118816
Chang, Lupo, Vigneron (PI). Role: Project 1 Leader
09/15/2024-08/31/2029
NIH/NCI
Imaging and Genomic Signatures of Brain Tumor Heterogeneity and Evolution to Optimize Patient Management

R01CA239288
Viswanath (PI); Role: Co-Investigator
02/11/2020–01/31/2025
NIH/NCI
Imaging telomere maintenance mechanisms in gliomas

R01CA163336
Song (PI); Role: Co-Investigator
12/01/2023–11/30/2028
NIH/NCI
Predicting Transcriptional and Epigenetic Networks in Cancer from Sequencing Data

T32CA151022
Costello (PI)
09/01/2015-08/31/2025
NIH/NCI
Training Program in Translational Brain Tumor Research

R35NS105068
Okada (PI); Role: Co-Investigator
12/01/2017 – 11/30/2025
NIH/NINDS
Preclinical development of breakthrough immunotherapy for brain tumors

R01CA244621
Oldham (PI); Role: Co-Investigator
12/01/2019 – 11/30/2024
NIH/NCI
Decoding the molecular basis of cellular identity in adult malignant gliomas

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2023-present	Scientific Advisory Board, Modifi Biosciences.
2021	Meeting Co-Chair, SNO Conference on Basic and Translational Omics of Brain Tumors and their Microenvironment
2020-present	Basic Science Advisor to the UCSF Neurosurgery Residents, PGY1-7
2019-present	Advisory Board, Benioff Initiative for Prostate Cancer Research
2018-2020	Scientific Advisory Board, Progenity Inc.
2018-2022	Chair, Research Allocation Program, Cancer, UCSF
2017-present	Executive Committee, Brain Tumor Center, UCSF
2016-present	Cofounder, Telo Therapeutics Inc., San Francisco, CA
2017-present	Executive Committee, Biomedical Sciences graduate program, UCSF
2015-present	Scientific Co-Director, Loglio Consortium
2015-2025	Director, NIH Training Program in Translational Brain Tumor Research

2014-2022 Chair, Research Oversight Committee, Genome Quebec Pediatric Brain Tumors
2013 Chair, Gordon Conference on Genetics and Epigenetics
2010 Professor, Department of Neurological Surgery, UCSF
2010- Editorial Board, Neuro-Oncology and Journal of Neuro-Oncology
2008-2014 Director, NIH Roadmap Epigenome Mapping Center
2006- Scientific Advisory Council, National Brain Tumor Society
2005 Karen Osney Brownstein Endowed Chair in Molecular Neuro-Oncology
2005 Associate Professor, Dept. of Neurological Surgery, UCSF
2005 Director, Epigenetics Division of the UCSF CCC Program in Cell Cycling and Signaling
2002-2014 Course Co-Director, Neurosurgery Residents Research Conference (monthly)
2000 Assistant Professor and PI, Dept. of Neurological Surgery, UCSF

Other Experience and Professional Memberships

2021-2023 Basic Science Representative, Society for Neuro-Oncology
2020- AACR-Novocure Grants and Fellowship Review Panel
2017 Co-Founder, Telo Therapeutics, Inc.
2014-present Meeting Committee, Society for Neuro-Oncology, Abstract Reviews
2015 *Nature* Discussion Group on the future of Epigenetics of Cancer and Aging
2014-present External Advisory Boards: Mayo Clinic Brain Tumor SPORE; University of North Carolina T32; University of Michigan Brain Tumor Center; Cleveland Clinic SPORE and T32 applications.
2012-2022 BC Genome Sciences Center, Associate Member
2010 AACR Special Conferences Committee, member
2010 International Human Epigenome Consortium (IHEC), member
2007 International Epigenome Project (AHEAD), committee member
2006 Nature, Editors Roundtable on the future of Epigenetics
2005 Human Epigenome Project committee

Honors

2024 Keynote Lecture, Christopher Davidson Forum, Washington University
2023 Keynote Lecture, Gordon Conference on Cancer Genetics and Epigenetics
2022 Featured Speaker, 19th Annual Retreat, Brain Tumor Center, Wake Forest
2022 Keynote Lecture, Annual Cancer Center Retreat, University of North Carolina
2020 Hans-Dietrich Herrmann Lecture 2020
2018 Research Highlighted by General Electric, Five Coolest Things on Earth This Week - Week 72
2016 Keynote Plenary Lecture, Society for Neuro-Oncology Annual Meeting
2016 Keynote Lecture, Stanford University Cancer Center Annual Retreat
2015 AIRC Lecture, 11th World Conference on The Future of Science
2014 Oncology Society Lecture, Mayo Clinic
2014 Keynote Lecture, EMBO Workshop on Epigenetic Plasticity, Portugal
2014 Keynote Lecture, ISCO meeting, Cancer Genome: From Structure to Function
2014 Keynote Lecture, Medulloblastoma in the Mountains
2013 Distinguished Lecture, DKFZ, Heidelberg
2013 Keynote Lecture, Inaugural Clinical Epigenomics Conference
2012 Keynote Lecture, European Association for Neuro-Oncology Annual Meeting
2010 Outstanding Research Achievement Award, by Nature Biotechnology

Grant Review Panels: NIH CG study section member, NIH BMCT (Ad Hoc), NCI U19 reviews, NIH Director's Early Independence Award panel, NIH Special Emphasis panels (6), Texas CPRIT, ACS, NBTS, Burroughs Welcome, AACR, and 12 additional agencies (national and international). UCSF Research Allocation Program (Chair), Marcus Precision Medicine grant program.

Reviewer for Journals: Science, Nature, Cell, Cancer Cell, NEJM, JAMA, Nature Genetics, PNAS, Neuro-Oncology, Acta Neuropathologica, and 36 additional journals.

C. Contributions to Science

1. We have been studying tumor immortality and evolution in low grade and high-grade brain tumors. Immortality is thought to be conferred by mutations in the TERT promoter, which are the third most

common mutation in human cancer. In Bell 2015, we discovered the transcription factor that is selectively recruited to the mutant TERT promoter across cancer types. Mancini et al, 2018 reports the discovery of the B1L-containing isoform of GABP as being critical for controlling TERT expression and immortality, selectively in GBM cells with the TERTp mutation. These studies led to founding of a Biotech company, Telo Therapeutics, and a partnership with GlaxoSmithKline Pharma. In 2021, Amen et al demonstrates strong synergy between GABPB1L reduction and temozolomide in reducing GBM growth in an orthotopic xenograft model, highlighting a potentially therapeutically relevant combination strategy. We collaborate with Dr. Solomon, most recently to understand the role of duplications in the TERT promoter across cancers (Barger, Suwala et al. 2022).

a. Bell RJ, Rube HT, Kreig A, Mancini A, Fouse SF, Nagarajan RP, Choi S, Hong C, He D, Pekmezci M, Wiencke JK, Wrensch MR, Chang SM, Walsh KM, Myong S, Song JS*, Costello JF*. The transcription factor GABP selectively binds and activates the mutant TERT promoter in cancer. Science. 2015 May 29;348(6238):1036-9. PMCID: PMC4456397. *co-corresponding authors.
b. Mancini A, Xavier-Magalhães A, Woods WS, Nguyen KT, Amen AM, Hayes JL, Fellmann C, Gapinske M, McKinney AM, Hong C, Jones LE, Walsh KM, Bell RJA, Doudna JA, Costa BM, Song JS, Perez-Pinera P, Costello JF. Disruption of the β1L Isoform of GABP Reverses Glioblastoma Replicative Immortality in a TERT Promoter Mutation-Dependent Manner. Cancer Cell. 2018 Sep 10; 34(3):513-528. PMID: 30205050. PMCID: PMC6135086.
c. Amen AM, Fellmann C, Soczek KM, Ren SM, Lew RJ, Knott GJ, Park JE, McKinney AM, Mancini M, Doudna JA*, Costello JF*. Cancer-specific loss of TERT activation sensitizes glioblastoma to DNA damage. PNAS, 2021, Mar 30;118(13). PMCID: PMC8020668.
d. Barger CJ*, Suwala AK*, Soczek KM, Wang AS, Kim MY, Hong C, Doudna JA, Chang SM, Phillips JJ, Solomon DA, Costello JF. Conserved features of TERT promoter duplications reveal an activation mechanism that mimics hotspot mutations in cancer. Nat Commun. 2022 Sep 16;13(1):5430. PMID: 36114166; PMCID: PMC9481613

2. Concurrently, we investigate patterns of human tumor evolution and the selective pressure of therapy on the emergent drivers of tumor recurrence. In Johnson 2014, we showed that a) tumor recurrence often originates from a very early ancestor of the primary tumor, and IDH1 mutation is the very first mutation b) chemotherapy induces hypermutation in IDH1 mutant tumors that can drive indolent low-grade glioma to aggressive high grade GBM. We participated in two additional studies on TMZ associated hypermutation and evolution (Campbell, 2018; GLASS, 2022). Although IDH1 mutation appears to initiate gliomagenesis, we discovered that the mutant allele may also be deleted during malignant transformation to higher grades (Mazor, 2017). Recently, we used a whole tumor sampling approach to elucidate the cellular and genetic roots of GBM (Mathur, 2024).

a. Johnson BE, Mazor T, Hong C, Barnes M, Aihara K, McLean CY, Fouse SD, … Berger MS, Chang SM, Taylor BS*, Costello JF*. Mutational Analysis Reveals the Origin and Therapy-Driven Evolution of Recurrent Glioma. Science. 2014 Jan 10; 343(6167):189-93. PMCID: PMC3998672.
b. Varn FS, Johnson KC, Martinek J, Huse JT, Nasrallah MP, Wesseling P, Cooper LAD, Malta TM, Wade TE…GLASS Consortium. Glioma progression is shaped by genetic evolution and microenvironment interactions. Cell. 2022 Jun 9;185(12):2184-2199.e16. PMID: 35649412; PMCID: PMC9189056.
c. Campbell BB, Light N, Fabrizio D, … Costello JF, Meyn MS, Pursell ZF, Malkin D, Tabori U, Shlien A. Comprehensive Analysis of Hypermutation in Human Cancer. Cell. 2017 Nov 16;171(5):1042-1056.e10. PMCID: PMC5849393.
d. Mathur R, Wang Q, Schupp PG, Nikolic A, Hilz S, Hong C, Grishanina NR, Kwok D, Stevers NO, Jin Q, Youngblood MW, Stasiak LA, Hou Y, Wang J, Yamaguchi TN, Lafontaine M, Shai A, Smirnov IV, Solomon DA, Chang SM, Hervey-Jumper SL, Berger MS, Lupo JM, Okada H, Phillips JJ, Boutros PC, Gallo M, Oldham MC, Yue F, and Costello JF. Glioblastoma evolution and heterogeneity from a 3D whole-tumor perspective. Cell, 2024 Jan 18;187(2):446-463.e16. PMID: 38242087; PMCID: PMC10832360.

3. I served as Director of the UCSF-based NIH Roadmap Epigenome Mapping Center, one of four centers funded by the NIH Directors office under the national Roadmap Epigenome project. Collectively with the 3 other mapping centers, we created and analyzed maps of reference epigenomes of a 111 human cell types and tissues (NIH Roadmap Epigenome Consortium, 2015; Elliott et al, 2015). Our group profiled ES cells,

placenta and adult male sperm cells, among many others. We also used our reference epigenome maps to define a new evolutionarily conserved role for tissue type specific DNA methylation (Maunakea et al, 2010).

a. Zhang B, Kim MY, Elliot G, Zhou Y, Zhao G, Li D, Lowdon RF, Gormley M, Kapidzic M, Robinson JF, McMaster MT, Hong C, Mazor T, Hamilton E, Sears RL, Pehrsson EC, Marra MA, Jones SJM, Bilenky M, Hirst M, *Wang T, *Costello JF, *Fisher SJ. Human placental cytotrophoblast epigenome dynamics over gestation and alterations in placental disease. Dev Cell. 2021 May 3;56(9):1238-1252.e5. Epub 2021 Apr 22. PMCID: PMC8650129.
b. The NIH Roadmap Epigenome Consortium. Integrative analysis of 111 reference human epigenomes. Nature, Feb 18, 2015, 19;518(7539):317-30. PMCID: PMC4530010.
c. Elliott G, Hong C, Xing X, Zhou X, Li D, Coarfa C, Bell RJ, Maire CL, Ligon KL, Sigaroudinia M, Gascard P, Tlsty TD, Harris RA, Schalkwyk LC, Bilenky M, Mill J, Farnham PJ, Kellis M, Marra MA, Milosavljevic A, Hirst M, Stormo GD, Wang T, Costello JF. Intermediate DNA methylation is a conserved signature of genome regulation. Nature Communications. 2015 Feb 18;6:6363. PMCID: PMC4333717.
d. Maunakea AK, Nagarajan, RP, … Hirst M, Wang T*, Costello JF*. Conserved Role of Intragenic DNA Methylation in Regulating Alternative Promoters. Nature, 2010 Jul 8;466 (7303): 253-7. * co-corresponding authors. PMCID: PMC3998662.

4. During my earlier years as an independent PI at UCSF, we contributed general principles (Zardo et al, 2002) and specific examples (Hong et al, 2007) of how genetic and epigenetic mechanisms are related to each other in human cancers and proposed an integrated model. Most prior research focused on genomics ignoring epigenomics, or vice versa. We have an ongoing project stemming from this earlier work, using high resolution, sequencing based methods for genomics and epigenomics in the same tumor samples collected over time. Based on the research of many groups since the advent of next-generation sequencing applied to cancer, genetic mutations in epigenetic regulators have become a major theme in many types of human cancer. Our studies and many others support the general concept that somatic mutations are a cause of cancers and altered epigenomic programming may be a common mechanism by which genetic alterations lead to cancer.

a. Hong C, Moorefield KS, Jun P, Aldape K, Kharbanda S, Phillips HS, Costello JF. Epigenome scans and cancer genome sequencing converge on WNK2, a kinase-independent suppressor of cell growth. Proc Natl Acad Sci USA, 2007, June: 104 (26), 10974-10979. PMCID: PMC1904113.
b. Ching T-T; Maunakea AK; Jun P; Hong C; Zardo G; Pinkel D; Albertson DG; Fridlyand J; Mao J-H; Shchors K; Weiss WA; Costello JF. Epigenome analyses using BAC microarrays identifies evolutionary conservation of tissue-specific methylation of SHANK3. Nature Genetics, 2005, June; 37, 645 - 651. PMID: 15895082.
c. Zardo G; Tiirikainen M, Hong C; Misra A; Feuerstein BG; Volik S; Collins CC; Lamborn KR; Bollen A; Pinkel D; Albertson, DG; Costello JF. Integrated Genomic and Epigenomic Analyses Pinpoint Biallelic Gene Inactivation in Tumors. Nature Genetics, 2002, 32(3):453-458. PMID: 12355068.
d. Hong C; Bollen AW; Costello JF. The contribution of genetic and epigenetic mechanisms to gene silencing in oligodendrogliomas. Cancer Research, 2003, 63: 7600-7605. PMID: 14633674.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/joseph.costello.1/bibliography/public/

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Prevention Peer Reviewer Appointment
February 2025

Name	Organization	Title	Expertise
Sherrie Wallington, Ph.D.	George Washington University School of Nursing	Associate Professor (Tenured)	cancer prevention, cancer disparities, health communication, and health literacy utilizing mixed methods and community-based participatory research

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: WALLINGTON, Sherrie Lee

eRA COMMONS USER NAME (credential, e.g., agency login): swallington7733

POSITION TITLE: Assistant Professor (Tenured), Health Disparities and Oncology, School of Nursing, Milken Institute School of Public Health, George Washington University, George Washington University Cancer Center

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of North Carolina, Greensboro, NC	BSHE	08/1984	Communication Arts
University of North Carolina, Greensboro, NC	MA	05/1990	Communications
Howard University, Washington, D.C.	PhD	08/2006	Mass Media/Health Communications
Harvard School of Public Health & Dana-Farber Cancer Institute	Postdoctoral Fellowship	05/2009	Cancer Prevention; Cancer Health Disparities
Johns Hopkins Graduate Summer Institute of Epidemiology and Biostatistics, Baltimore, MD	Summer	06/2012	Randomized Clinical Trials
Duke University, Durham, NC	Certificate	08/1995	Nonprofit Management
National Cancer Institute Multi-Level Training Institute (Initially scheduled in Alabama and Maryland; now virtual due to COVID-19)	Certificate	09/2020	Multi-level interventions
National Institutes of Health R01 Coaching Program	Certificate	12/2020	R01 submission and resubmissions

A. Personal Statement

I am a disparities and community-engaged researcher with specialized knowledge in cancer prevention, cancer disparities, health communication, and health literacy utilizing mixed-methods and community-based participatory research. I grew up in rural Stokesdale, North Carolina, and am the first person in my family to reach this level of education. The distance alone that it took my family to get to a major comprehensive hospital back then was approximately 2 to 3 hours. Thus, place does matter and can promote geographical disparities and exacerbate the social determinants of health and equitable access to care. Thus, I have firsthand knowledge and see through a very personal lens the devastation of chronic diseases, disparities, systems, and structures which result in health inequities, particular among communities of color.

I approach my research through theory-driven and social determinant of health and health equity lenses with consideration given to community engaged participatory research and intersectionality lenses. A central focus of my work also emphasizes the role of trust, health communication, and health literacy toward the goal of health equity for marginalized communities. I arch writing at Bowie State University, Howard University, Georgetown University, and Winston-Salem State University. Currently, at GW School of Nursing, I teach a doctoral level qualitative and mixed methods research course and in 2022. Developed the GW School of Nursing's first doctoral level social determinants of health course.

I have approximately 15 years' experience engaging marginalized communities in Boston, MA and the District of Columbia establishing community advisory boards, engaging communities from concept development, implementation, and dissemination. In addition, I am an experienced principal investigator, co-investigator, project leader, and evaluator as part of community engagement cores (Harvard/Dana Farber U54; Georgetown P60; Hopkins U54), evaluation study teams (Hampton University, U54) for the National Institutes of Health (NIH) and the National Cancer Institute (NCI), National Institutes Minority Health Disparities (NIMHD) and Health Resources and Services Administration (HRSA). Further my work is supported by support from foundations--American Cancer Society, Robert Woods Johnson Foundation and the Prevent Cancer Foundation.

My research has also served as a benchmark for other notable research and policy endeavors. I have had the privilege to present on women's health and community-engaged strategies on Capitol Hill twice at the invitation of U.S. Congresswoman Lucille Roybal-Allard for the Prevent Cancer Foundation's Legislative Day and have twice served as a panelist on NPR's Diane Rhem Show, speaking on engaging D.C. communities around mothers, adolescents, and HPV vaccination.

These experiences and core competencies have prepared me for this leadership role as principal investigator. Through my personal and academic experiences and also my trainings through coaching and training through the National Institutes of health as noted above, I have developed strong skills in study design (randomized controlled trials, longitudinal studies, and cross-sectional, mixed method—qualitative and quantitative), community-engaged research, project management and implementation, clinical trial accrual and enrollment, human subjects' research ethics, and dissemination strategies beyond just peer-reviewed publications.

Ongoing and recently completed projects that I would like to highlight include:

R25NR021373— National Institutes of Health and the National Institute of Nursing Research
Wallington, SF (PI)
Dates of Award: 07/01/2024–06/30/2027
"Advancing Social Determinants of Health Research through a CBPR and Intersectionality Lens: A Short Course"

1184990—Prevent Cancer Foundation
Wallington, SF (PI)
1/15/2024 - 1/14/2026
"Breast Density and Me" A Pilot Educational Intervention

AY2022-23—George Washington University, Office of the Vice Provost of Research
Wallington, SF (PI)
10/31/2022 – 11/01/2023
What's in Your Determinants of Health Toolbox? Interdisciplinary Approaches Across the Campus and the Community

7795—RWJF Interdisciplinary Leader Program-Cohort 5
Wallington, Yang (Co-I), Staley (Co-I)
08/01/2019-07/31/2020
It is A Dad Thing: Fathers as Powerful Agents of Change in Reducing Disparities in Maternal Mortality in the District of Columbia

39196-NIH/CTSI-Children's/GWU
Wallington; Sherrie (PI)
06/01/2019 – 06/30/2020
Care Coordination in Patient Adherence to Breast Cancer Treatment: A Mixed Methods Exploration of Reasons for Disparate Breast Cancer Mortality in the Nation's Capital

80000954—State of Rhode Island
Cummings (PI)/Greaney/Wallington (Co-I)

09/01/2018 – 08/01/2021
Building Health Literacy in Federally Qualified Health Center Caring for Homeless Patients

Citations:

1. Glenn A, Smith PJ, **Wallington SF** (2024). A nurse-led approach to testing and adapting a telehealth guide for e-empathy in goals of care conversations for Black patients with chronic kidney disease. Patient Educ Couns. 131:108593. doi: 10.1016/j.pec.2024.108593. Epub ahead of print. PMID: 39626453.

2. Smith PJ, **Wallington SF**. (2024). Disparities in Cervical Cancer Knowledge and Trust in Information Sources Among Diverse American Women. J Cancer Educ. 2024 Nov 6. doi: 10.1007/s13187-024-02534-6. Epub ahead of print. PMID: 39503944.

3. **Wallington, S. F**., Keston, K., Athey, E., & Kokkinogenis, K. M. (2024). What's in your social determinants of health teaching toolbox? Nursing pedagogical considerations. Journal of Professional Nursing, 54, 29–35. https://doi.org/10.1016/j.profnurs.2024.06.004

4. Posey, L., **Wallington, S. F**., Sikka, N., Pericak, A., Zhou, Q., & Pintz, C. (2024). Evaluating a virtual flipped classroom approach to nurse practitioner telehealth competency development. Journal of Nursing Education, 63(8), 546-551.

5. Robien K, Clausen M, Sullo E, Ford YR, Griffith KA, Le D, Wickersham KE, **Wallington SF.** Prevalence of Food Insecurity Among Cancer Survivors in the United States: A Scoping Review. J Acad Nutr Diet. 2023 Feb;123(2):330-346. doi: 10.1016/j.jand.2022.07.004. Epub 2022 Jul 12. PMID: 35840079.

B. Positions, Scientific Appointments, and Honors

2022-current	Associate Professor, Health Disparities and Oncology (Tenured), George Washington School of Nursing, Washington, DC, July 2022–current.
2018-2022	Assistant Professor, Health Disparities and Oncology, George Washington University School of Nursing, Milken Institute of Public Health, and the George Washington Cancer Center, Washington, D.C.
2017-current	Adjunct Assistant Professor, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington, D.C.
2011-2017	Assistant Professor of Oncology, Program Director, Health Disparities Initiative, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington, D.C.
2006-2009	Postdoctoral Fellow, Harvard School of Public Health & Dana Farber Cancer Inst., Boston, MA.
2005-2006	Director, Distinguished Scholars Summer Program, Howard University Science, Engineering, and Mathematics Program, Washington, D.C.
2005-2006	Assistant Director, Howard University Science, Engineering and Mathematics Program, Washington, D.C.
2002-2004	Graduate Assistant, Annenberg Honors Program, John J. Johnson School of Communications, Howard University, Washington, D.C.
1998-2002	Assistant Director, Honors College, Winston-Salem State University, Winston-Salem, NC

Other Experience and Professional Memberships

2010-present	Member, Society of Behavioral Medicine
2009-present	Member, American Public Health Association
2009-present	Member, American Association for Cancer Research

Teaching Appointments

Summer 2020	Instructor/Course Coordinator—Doctoral Level Course—NURS 8446—Qualitative Research Methods, NURS 8430 Determinants of Health (Does no duplicate the proposed short course)
Fall 2019	Instructor/Course Coordinator, NURS6207-Master's-level course—Evidence-based Practice Research, School of Nursing, George Washington University.
2012-2017	Course Director, Lombardi Comprehensive Cancer Center, Georgetown School of Medicine, Washington, D.C., Minority Populations & Health Disparities (Tumor Biology Program (TBIO-561)).
2005-2006	Adjunct Instructor, Department of Mass Communications, Bowie State University, Bowie, Maryland, *Oral Communications and Research Methods*.
2004-2005	Adjunct Instructor, College of Medicine, MPH Program, Howard University, Washington, D.C., *Introduction to Research Writing–Summer Bridge Course.*
2004-2005	Graduate Teaching Assistant (with full course responsibility) – J.H. Johnson School of Communications, Department of Radio, Television & Film, Howard University, Washington, D.C., *History of Broadcasting & Film* and *Survey of Communication Research*.
1995-2002	Adjunct Instructor, Department of Mass Communications, Winston-Salem State University, Winston-Salem, NC, *Principles of Advertising, Creating Ad Messages*, and *Public Relations*

Honors and Distinctions

2020	George Washington University School of Nursing, Faculty Civility Award
2019	Robert Woods Johnson Foundation (RWJF) Peer Mentoring Award, RWJF New Connections Program,
2009-	NIH Health Disparities Loan Repayment Program, Health Disparities Research.
2007	American Association for Cancer Research (AACR) Minority Scholar in Cancer Research Award *the Science of Cancer Health Disparities in Racial/Ethnic Minorities & Medically Underserved*.
2006-2009	National Cancer Institute Research Supplement to Promote Diversity in Health-Related Research Award.
2006	Top Young Scholar Award, Kentucky Conference on Health Communication, Lexington, KY.
2006	Travel Award, Kentucky Conference on Health Communication, Lexington, KY.
2004	Student Scholarship Award, Cancer on the Internet Conference, sponsored by the European School of Oncology, Milan, Italy, and NY.
2003	Carter J. Woodson Graduate Scholarship Award, Shiloh Baptist Church, Washington, D.C.
2002	Congressional Black Caucus Spouses' Scholarship Award, Washington, D.C.
2002-2006	Howard University Graduate Assistantship, Howard University, Washington, D.C.

C. Contributions to Science

1. I have been fortunate to conduct population and community engaged interventions focusing on cancer and as part of large scientific teams on NIH-funded awards with some top investigators. This line of research focused on community engagement, prevention, disparities, and clinical trial accrual among minority underserved groups.
    a. Tucker-Seeley RD, **Wallington SF**, Canin B, Tang W, McKoy JM. Health Equity for Older Adults with Cancer. *J Clin Oncol*. 2021 Jul 1;39(19):2205-2216. doi: 10.1200/JCO.21.00207. Epub 2021 May 27. PMID: 34043411.
    b. **Wallington S**, Oppong B, Dash C, Coleman T, Greenwald H, Torres T, Iddirisu M, Adams-Campbell LL. A Community-Based Outreach Navigator Approach to Establishing Partnerships for a Safety Net Mammography Screening Center. *J Cancer Educ*. 2018 Aug;33(4):782-787. doi: 10.1007/s13187-016-1152-9. PMID: 27995458; PMCID: PMC5940570.
    c. **Wallington SF**, Dash C, Sheppard VB, Goode TD, Oppong BA, Dodson EE, Hamilton RN, Adams-Campbell LL. Enrolling Minority and Underserved Populations in Cancer Clinical Research. *Am J Prev Med*. 2016 Jan;50(1):111-117. doi: 10.1016/j.amepre.2015.07.036. Epub 2015 Oct 21. PMID: 26470805; PMCID: PMC4691547.
    d. **Wallington SF**, Luta G, Noone AM, Caicedo L, Lopez-Class M, Sheppard V, Spencer C, Mandelblatt J. Assessing the awareness of and willingness to participate in cancer clinical trials among immigrant Latinos. *J Community Health*. 2012 Apr;37(2):335-43. doi: 10.1007/s10900-011-9450-y. PMID:
2. I also have specialized knowledge examining the role of health literacy, health communication, media, and communication and web-based technologies as relates to prevention, health disparities, message framing, and dissemination. These type studies are important in creating awareness of chronic diseases and disparities. In one

study, I directed an exploratory analysis to qualitatively describe barriers facing health journalists when covering health disparities in local media. News coverage of health topics influences knowledge, attitudes, and behaviors at the individual level, as well as agendas and actions at the institutional and policy levels. Because disparities in health often are the result of social inequalities that require community-level or policy-level solutions, news stories employing a health disparities news frame may contribute to agenda-setting among opinion leaders and policymakers and lead to policy efforts aimed at reducing health disparities. Our results revealed journalists consider several angles when developing health stories, including public impact and personal behavior change. Some journalists reported that disparities-focused stories are "less palatable" for some audiences. Public health practitioners may use these findings to inform communication, translation, and dissemination efforts with local media to advance the public dialogue about health disparities.

a. Greaney ML, **Wallington SF**, Rampa S, Vigliotti VS, Cummings CA. Assessing health professionals' perception of health literacy in Rhode Island community health centers: a qualitative study. BMC Public Health. 2020 Aug 26;20(1):1289. doi: 10.1186/s12889-020-09382-1. PMID: 32843002; PMCID:
b. **Wallington SF**, Oppong B, Iddirisu M, Adams-Campbell LL. (2018). Developing a mass media campaign to promote mammography awareness in African American women in the nation's capital. *J Community Health.* 2018;43(4):633–8.
c. **Wallington SF**, Blake K, Taylor-Clark K, Viswanath K. (2010). Antecedents to agenda setting and framing in health news: an examination of priority, angle, source, and resource usage from a national survey of U.S. health reporters and editors. *J Health Comm*. 2010;15(1):76–94. doi:10.1080/10810730903460559
d. **Wallington SF**, Blake KD, Taylor-Clark K, Viswanath K. Challenges in covering health disparities in local news media: an exploratory analysis assessing views of journalists. *J Community Health* 2010;35(5):487–94. doi:10.1007/s10900-009-9217-x.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/myncbi/sherrie.wallington.1/bibliography/public/

Product Development Research Peer Reviewer Appointments
February 2025

Name	Organization	Title	Expertise
Pamela Carroll, PHD	Isomorphic Labs	Chief Operating Officer	AI, drug development, immunology, oncology, cell and development biology
Joseph A. Leveque, MD	MEDIKINE	President and CEO	Oncology, immunology, and neurology, clinical development, regulatory affairs, pharmacovigilance, finance
Lucy Liu, PHD	Longwood Fund	Principal	Neuron development and metabolism, venture capital investment, biotech startup strategy, fundraising
Uciane K. Scarlett, PHD	Stealth	Investor	Investment, oncology, gene therapy, immunology
Adrian Woolfson, PHD	Replay Holdings, INC	Founder, Executive Chairman, and President	Gene and cell therapy, synthetic biology, virology, oncology, immuno-oncology

Pamela Carroll, Ph.D.

Boston, MA ▪ +1 617-595-2040 ▪ pamcarrollbio@gmail.com

PROFILE

Seasoned executive with a proven ability to drive innovation and growth in pharma and biotech. Leadership roles in R&D, corporate business development and operations in pharma and biotech industries. LinkedIn

- A successful track record in company building and business development including a robust history of deal execution and demonstrated ability to execute innovative and transformational deals
- Strengths in strategy: corporate, business development and portfolio
- Led large oncology drug discovery organizations in pharma, biotech and academic centers. Led multiple programs into Ph1 resulting in two marketed products
- Developed experitise in the discovery and development of small molecules, biologics, therapeutic vaccines and adoptive cell therapies
- Leader in applying AI and new technology platforms to advancement of new medicines
- Leverages strong networks across academics, industry and venture in US and Europe
- Significant experience with Board and investor interactions

PROFESSIONAL EXPERIENCE

ISOMORPHIC LABS- London **2022–present**

Chief Operating Officer (transitioned to strategic advisor in 10/2024)

An early-stage biotech using an AI-powered platform to discover new therapeutics. Funded by Alphabet. Company founded on an exclusive license to Alphafold, the breakthrough protein folding prediction model

- Leads business development, corporate strategy, legal, finance, communications, HR and operations as the company grew from 70 to 150 FTEs
- Works closely with CEO (Sir Demis Hassabis, 2024 Nobel Laurate in Chemistry), the executive team and Board to aggressively build a leading AI-driven therapeutics company
- Led execution of strategic partnerships with Eli Lilly and Novartis receiving $82.5M in upfronts and $3 billion in potential value. Isomorphic Labs announcement
- Led communication strategy for publication of Alphafold 3 (Nature paper press release) covered by global press including interviews with NYT, Financial Times and Endpoints
- Led a successful fundraise with Alphabet, the sole investor
- Works closely with CSO to develop an oncology and immunology focused portfolio
- Works closely with CTO to support AI platform, including building a vast compute infrastructure.
- Developed corporate, business development and portfolio strategy
- Builds SAB, KOL and consultant networks for the company

ROIVANT DISCOVERY (closed Sept. 2022) **-** Boston, MA and New York City **2020– 2022**

Chief Business Officer

SILICON THERAPEUTICS (acquired by Roivant)

President and Chief Business Officer

An AI and physics-driven drug discovery biotech developing novel small molecule therapeutics.

- Drove strategic partnering
  - Executed platform collaboration with Amgen
  - Led partnering, negotiations, and due diligence with major IO pharma on early-stage program.
  - Achieved a clinical collaboration agreement with Merck to evaluate combination of pembrolizumab and Silicon Therapeutic's clinical program.
  - Led in-licensing discovery stage assets
- Supported the $450M acquisition by Roivant and spun-off the clinical program into a new company
- Led commercial assessment, competitive landscape and KOL outreach
- Initiated diversity and inclusion efforts across Roivant organization

GENOCEA BIOSCIENCES - Cambridge, MA **2016-2020**

Senior Vice President, Oncology

A company that developed therapeutic vaccines and cell therapies for infectious disease and cancer

- Established and directed company's oncology pipeline in personalized vaccines and cell therapies
- Drove strategic partnering and in-licensing technologies
- Established and led scientific advisory board and KOL networks
- Represented company to Board of Directors, at conferences, potential strategic partners, and investors

JOHNSON AND JOHNSON INNOVATION – Cambridge, MA **2013-2016**

Vice President, Oncology

- Developed and executed oncology and immuno-oncology partnerships with external partners spanning small and large molecule, and oncolytic virus projects
- Led opportunities for seed investment, newco formation, R&D collaborations and partnerships
    - Launched 50M Series A with JNJ venture (acquired by Novartis)
    - Established and led multiple academic collaborations
    - Established T cell-redirection bispecific partnerships with multiple biotechnology companies

ROCHE PHARMA AND RESEARCH DEVELOPMENT (site closure) – Nutley, NJ **2011-2013**

Vice President, Oncology Discovery

- Led Roche small molecule portfolio and strategy including development of vemurafenib (marketed as Zelboraf)
- Directed programs from target selection to IND including translational research

BELFER INSTITUTE FOR APPLIED CANCER SCIENCES, DANA FARBER CANCER INSTITUTE, HARVARD MEDICAL SCHOOL

Founding Head of Research **2008-2011**

- Initiated and led drug discovery pharma collaborations (>$40M in pharma support).
- Directed leaders of target discovery and validation, drug discovery biology, oncogenomics, bioinformatics and research operations.

MERCK RESEARCH LABORATORIES- Boston, MA **2004-2008**

Director and Department Head, Cancer Pathways (1 promotion)

- Responsible for preclinical biology and building a team of 30 FTEs
- Managed group that led programs in developing niraparib (marketed as Zejula), and to early-stage clinical trials in mTOR, IGFR and Notch pathway
- Pioneered innovative translational research platforms that integrated genomic, complex models and clinical data

BRISTOL-MYERS SQUIBB – Princeton, NJ **1998-2004**

Senior Research Scientist, Applied Genomics (3 promotions)

- Instituted new technologies that included genetic screens and high content cell biology
- Drove major collaboration with Exelixis that delivers novel targets into the portfolio

STANFORD UNIVERSITY **1994-1998**

Postdoctoral Fellowship

- Identified a novel signal transduction tyrosine kinase pathway that led to a first author Cell paper
- National Service Award postdoctoral fellowship

EDUCATION

Doctor of Philosophy, **STONY BROOK UNIVERSITY**, Cellular and Development Biology
Advisor: Sidney Strickland

Bachelor of Science, **SAINT MICHAEL'S COLLEGE,** Biology
Presidential Award for Academic Excellence, Academic Hall of Fame inductee

JOSEPH A. LEVEQUE, MD

PROFESSIONAL EXPERIENCE

MEDIKINE, Menlo Park and San Diego, CA
President and Chief Executive Officer
January 2023 to Present
President and Chief Medical Officer
January 2022 to December 2022

Responsible for all executive functions including research, clinical development, pharmacovigilance and safety risk management, regulatory sciences, quality assurance, biometric, legal, finance and related activities focused on the Medikine pipeline including an interleukin (IL) 7 receptor agonist, a "dead" decoy receptor IL-18 receptor agonist, a cis-acting anti-PD-1 plus IL-2 /IL-15 beta gamma receptor agonist, and a dual IL-7 receptor plus IL-2/IL-15 beat gamma agonist. Participated and led private financings.

MIRATI THERAPEUTICS, La Jolla, CA
Chief Medical Officer
May 2020 to November 2021

Responsible for all clinical development, pharmacovigilance and safety risk management, regulatory sciences, quality assurance, and biometric activities focused on the MIRATI pipeline including KRAS G12C and G12D inhibitors, Dual TAM VEGF-2 inhibitor, PMRT5 inhibitor, SHP2 inhibitor, and SOS1 inhibitor. Participated in supplement public financings, dialog pre- and post-financing with investment analysts, and merger/acquisition (M&A) activities.

SYNTHORX, A Sanofi Company, La Jolla, CA
Chief Medical Officer
July 2018 to May 2020

Responsible for all clinical development activities, medical and scientific affairs functions and regulatory interactions focused on the SYNTHORX pipeline including synthetic biology-derived ("Synthorins") immunocytokine therapeutics of interleukin-2 (IL-2), interleukin-10 (IL-10), and interleukin-15 (IL-15). Participated in private and public financings (IPO), dialog pre- and post-financing with investment analysts, and M&A activities.

ARMO BIOSCIENCES, An Eli Lilly Company, Redwood City, CA
Chief Medical Officer
October 2017 to June 2018

Responsible for all research and development activities and regulatory interactions focused on the ARMO pipeline including immunocytokine therapeutics (IL-10, AM0010, pegilodecakin; IL-12 (AM0012); IL-15 (AM0015) and immune checkpoint inhibitors (AM0001, anti-PD-1; AM0003, anti-LAG-3). Participated in private and public financings (IPO), dialog pre- and post-financing with investment analysts, and M&A activities.

PROFESSIONAL EXPERIENCE (continued)

EMD SERONO (a business of Merck KGaA, Darmstadt, Germany), Rockland, MA
Head, North America Medical
Chief Medical Officer – United States
September 2015 to September 2017

Responsible for providing strategic leadership of an integrated US Medical enterprise with cross-portfolio development and commercialization responsibilities for neurology, immunology, oncology, immunooncology, endocrinology and reproductive health assets

BRISTOL-MYERS SQUIBB, Plainsboro and Lawrenceville, NJ
Vice President
Head, US Medical – Oncology (USMO)
September 2011 to September 2015

Responsible for providing strategic leadership and the tactical implementation of launch and life cycle management programs of an integrated US Medical Oncology enterprise with cross-portfolio development and commercialization responsibilities for immunooncology assets Opdivo® (nivolumab) and Yervoy® (ipilimumab), hematology assets Sprycel® (dasatinib) and Empliciti® (elotuzumab), and oncology assets Erbitux® (cetuximab), and Ixempra® (ixabepilone)

ONYX PHARMACEUTICALS, South San Francisco, CA
Vice President
Global Medical and Scientific Affairs (MedSA)
July 2009 to September 2011

Led an integrated Medical Scientific Affairs (MedSA) function that supported the late-stage development and commercialization activities for Kyprolis® (carfilzomib) including the origination, conceptualization, design and implementation of the ASPIRE and ENDEAVOR phase 2 studies. Also provided support for the late stage development and commercialization of Nexavar®, an asset in equal partnership with Bayer Schering Pharma licensed in nearly 100 Countries worldwide for advanced renal cell carcinoma and liver cancer. Additionally, participated in the development of Nexavar® for expanded indications in hepatocellular carcinoma and renal cell carcinoma and new indications for non-small cell lung cancer, breast cancer, colorectal cancer. and thyroid cancer. Participated in supplemental public financings, dialog pre- and post-financing with investment analysts, and M&A activities.

CEPHALON, Inc., Frazer, PA
Vice President
Oncology Medical and Scientific Affairs (MedSA)
May 2007 to July 2009

Cephalon was a publicly held company focused on the development and commercialization of novel central nervous system, cancer and immunologic therapeutics purchased in 2011 by TEVA. In 2006, Cephalon created a North American-based oncology business unit around the purchase of Trisenox, an arsenic trioxide derivative approved for the treatment of relapsed acute promyelocytic leukemia (APL) and investigated across a number of hematologic malignancies and solid tumors. In 2007, Cephalon purchased Salmedix and its primary asset, bendamustine-HCL (Treanda). In 2008, the Cephalon oncology business unit launched Treanda for chronic lymphocytic leukemia (CLL) and later that year for non-Hodgkin's lymphoma (NHL). Participated in M&A activities.

PROFESSIONAL EXPERIENCE (continued)

AMGEN, Inc., Thousand Oaks, CA
Medical Director - Nplate® (AMG 531) and Neulasta®

Focused on supportive care with an emphasis in growth factors for treating chemotherapy-induced neutropenia, myelodysplastic syndrome associated thrombocytopenia, and idiopathic thrombocytopenia purpura. Participated in M&A Activities.
February 2005 to May 2007

MOLECULAR HEALTH (formerly SCIENTIA, Inc., and LIFE BioSystems), Heidelberg, Germany
Founder and President
June 2000 to February 2005

SALICK HEALTH CARE, Inc., /BENTLEY HEALTH CARE, Inc., Beverly Hills, CA
Senior Vice President, Strategic Planning and Business Development
June 1997 to May 2000

LASH GROUP HEALTHCARE CONSULTANTS, Washington, D.C. & Foster City, CA
Principal
June 1996 to May 1997

HEALTH TECHNOLOGY ASSOCIATES, Washington, D.C.
Principal
June 1994 to May 1996

MERCK & Co., Rahway, NJ, and West Point, PA
MD/MBA Fellow
September 1990 to June 1994

MEDICAL TRAINING

UCLA CEDARS-SINAI MEDICAL CENTER, Los Angeles, CA
Resident Physician, Internal Medicine
June 1987 to June 1990

MEDICAL LICENSURE

California, 1988 to Present (Active)
New York, 1998 to 2002 (Inactive)
New Jersey, 1998 to 2002 (Inactive)
Pennsylvania, 1990 to 1995 (Inactive)

EDUCATION

UNIVERSITY OF PENNSYLVANIA - The Wharton School, Philadelphia, PA
Master of Business Administration (MBA)
September 1990 to June 1992

UNIVERSITY OF TEXAS MEDICAL SCHOOL, Houston, TX
Medical Doctorate (MD)
September 1983 to May 1987

SANTA CLARA UNIVERSITY, Santa Clara, CA
Bachelor of Sciences and Arts with Distinction, Biology (major) and Mathematics (minor)
September 1979 to June 1983

UNIVERSITY OF NEVADA AT LAS VEGAS, Las Vegas, NV
Mathematics
September 1978 to June 1979

LUCY LIU PH.D.

luliuphd@gmail.com

PROFESSIONAL EXPERIENCES

Longwood Fund
Principal
July 2022 – Present

Senior Associate
July 2020 – July 2022

Member of the Longwood Fund investment team with ~$850M AUM

- Source and diligence investment opportunities across all modalities and therapeutic areas. LP management.
- **Led diligence efforts on LF investments:** Engrail Therapeutics (2024), Progentos Therapeutics (2024), AAVantgarde Therapeutics (2023)
- **Companies cofounded at Longwood:** Stealth NewCo (2024, TCE company), Carbon Biosciences (2022), Tome Biosciences (2021)
- **Board Director:** Carbon, AAVantgarde
- **Board Observer:** Pulmocide, Progentos

Carbon Biosciences
VP, Strategy + Operations
July 2021 – Sept 2022

Longwood Fund founded newco that uses non-AAV parvoviruses as gene delivery vectors targeting the lung, heart, and other hard to reach tissues while de-targeting liver.

- ***Fundraising:*** Led strategy, pitch calls, diligence and data room efforts to raise a $38M series A (Agent, Longwood, Astellas, Camford, Solasta and UTokyo IPC)
- ***Strategy:*** Led indication prioritization, BD outreach and strategic prioritization of pipeline vectors. Presented at and assembled deck for first two board meetings after financing.
- ***Operations:*** Sourced and hired initial 15 employees across several functions including branding, facilities, HR and media

ImmuneID
Head of Strategy
Dec 2020 – June 2021

Longwood Fund founded newco built on a high throughput discovery engine that enables precision immunology by profiling serum, plasma and other biospecimens with origins from the Elledge's lab at Harvard Medical School

- ***Fundraising***: Led all pitch and diligence calls to raise a total of ~$70M across seed and series A seed financing (Arch + Longwood, Pitango, Xfund and In-Q-Tel).
- ***Strategy***: Led indication prioritization efforts focusing on antibody driven autoimmunity, leading biospecimen sourcing as the basis of company target ID. Brokered collaboration between ImmuneID and Mt. Sinai BioMe for biospecimen deal.
- ***Operations***: Directly responsible for recruiting, branding, facilities, and culture. Assisted in budgeting, press, and others.

Fellow
5AM Ventures
Jan 2020 – June 2020

- Leveraged scientific expertise to ideate and assist in a metabolism focused newco build with 4:59, 5AM's internal newco formation initiative.
- Worked with broader team to diligence Series A investment opportunities.

EDUCATION AND TRAINING

Damon Runyon Postdoctoral Fellow
Harvard Medical School

Trained with Norbert Perrimon (HHMI, NAS, AAAS)

- Secured 4 years of research funding ($250K) from the Damon Runyon Cancer Research Foundation.

Neurodegeneration Consortium (NDC)

$25M funded collaboration between MD Anderson, BCM, Mt Sinai and MIT for Alzheimer's research

- Scientific input and research that eventually contributed to the creation of Magnolia Neurosciences.

PhD Candidate
Baylor College of Medicine

Trained with Hugo Bellen (HHMI, NAS, AAAS, Gruber Prize)

- Published 2 first-author papers in *Cell* and *Cell Metabolism*. Cited over 1300 times since 2015.
- Scientific reviewer for publications in *Genetics* and *Scientific Reports*

Undergraduate
UNC Chapel Hill

Graduated with Honors

SKILLS AND INTERESTS

Technical: technical due diligence, license negotiation strategic planning, venture financial modeling, conflict resolution, mentorship **R&D:** preclinical study design, CRO management, project management, talent acquisition. **Interests:** hobby photographer, nature enthusiast, science communication

HONORS AND AWARDS

Larry Sandler Memorial Award (link)	Genetics Society of America
Damon Runyon Postdoctoral Fellowship (link)	Damon Runyon Cancer Research Foundation
Harold M. Weintraub Graduate Student Award (link)	Fred Hutch Cancer Research Center
Houston Women Leaders Forum	McKinsey & Company

PUBLICATIONS

1. Hagelkruys A*, Fell C*, Cicvaric A, **Liu L**, Li J, Horrer M, Stadlmann J, Polyansky A, Andersen T, Scaramuzza A, Wirnsberger G, Holmskov U, Perrimon N, Zagrov B, Quiroga F, Moeller J, Penninger J, Mereiter S, Nagy V. FIBCD1 is an endocytic GAG receptor associated with a novel neurodevelopmental disorder. ***EMBO Molecular Medicine, 2023.***
2. **Liu L**, MacKenzie KR, Putluri N, Maletić-Savatić M, Bellen HJ. The glia-neuron lactate shuttle and elevated ROS promote lipid synthesis in neurons and lipid droplet accumulation in glia via APOE/D. ***Cell Metabolism*. 2017.**
3. Chao HT*, **Liu L***, Bellen HJ. Building dialogues between clinical and biomedical research through cross-species collaborations. ***Semin Cell Dev Biol.* 2017**. PMID: 28579453. *EQUAL CONTRIBUTION
4. **Liu L**, Zhang K, Sandoval H, Yamamoto S, Jaiswal M, Sanz E., Li Z, Hui J, Graham BH, Quintana A, Bellen HJ. Glial lipid droplets and ROS induced by mitochondrial defects promote neurodegeneration. ***Cell*. 2015**.
5. Onyenwoke RU, Forsberg LJ, **Liu L**, Williams T, Alzate O, Brenman JE. AMPK directly inhibits NDPK through a phosphoserine switch to maintain cellular homeostasis. ***Mol Bio Cell***. **2012**.

Uciane K. Scarlett, Ph.D.

, Boston, MA 02118 • Phone: 347-255-6858 • email: uciane.scarlett@gmail.com

PROFESSIONAL EXPERIENCE

Investor, *Stealth – Company Creation & Investment Firm,* Boston, MA **2024 – present**

- Investment firm focused on company creation & syndication
- Co-founder & interim CEO of stealth newco: Xact Bio

Principal, *MPM Capital – Company Creation & Investment Firm,* Boston, MA **2021 – 2024**

- Interim CEO: Crane Biotherapeutics (pending M&A; >12x return)
- Company creation/ops & new investments: ashibio (Seed, Series A), Crane Biotherapeutics (Seed)
- BoD: ProRavel, Crane Biotherapeutics, TUO Therapeutics
- Fund Management: Dana Farber Cancer Institute (DFCI) $100M INV Fund, & relationship management
- LP Management: Lead for 2 global biopharma, Co-lead for 1 global biopharma
- Chaired investment meetings across main funds – OIF, BV
- Led several company creations to TS/late stage (e.g. Next-gen biologics, RNA delivery, iPSC) & driving significant deal flow (e.g. conceptualized & led firm-wide effort for late-stage deal opportunities)
- Leading several firm-wide initiatives geared towards firm visibility and academic interactions

Principal, *OSE – Company Creation & Investment Firm w/ $1B raised in 2015,* Oxford, UK **2019 – 2021**

- Co-lead of life sciences sector; talent, investment strategy development, and portfolio management
- BoD: T-Cypher Bio (Exec Chair), PepGen (NASDAQ; PEPG), MiroBio [acq'd Gilead], DJS [acq'd AbbVie], Scenic Bio
- Company creation/ops & new investments: T-Cypher Bio (~$8M Seed/closed $45M Srs A), Orfonyx (~$8M Seed), Alethiomics (~$8M Seed)
- Led $45M Series A & follow-on $112M Series B financing for PepGen (NASDAQ; PEPG)
- Led/co-led corporate re-structuring of two (2) portfolio companies – Orbit & Dark Blue Tx (Lab282)
- Created the role of Scientist-in-Residence (SIR); recruited first industry (Immunocore) experienced SIR for OSE
- Evolved EIR model and framework for life sciences; recruited first industry (AZ) experienced EIR for OSE
- Launched and organized OSE's inaugural Equity Analysts Showcase
- Drove and maintained US co-investor relationships via various initiatives
- Several industry thought leadership roles: Timmerman Report writer; founder/organizer Emerging Frontiers in Oncology

Atlas Venture – Company Creation & Investment Firm, Cambridge, MA **2018 – Dec 2019**

Entrepreneur-in-Resident

- Operating within seed-stage company, Korro Bio, and publicly listed company AVROBIO [NASDAQ]
- Korro: financing, corporate strategy, program development, licensing & partnering activities; report to Chair of Board
- AVROBIO [NASDAQ]: portfolio/pipeline strategy, commercialization strategy & plan (e.g. manufacturing/distribution); reported to CBO & CEO

Associate

- Team that built & operated Quench Bio and Dyne Therapeutics (NASDAQ; DYN), including Seed and Series A financings
- Board observer: Dyne Therapeutics, Quench Bio, and Navitor
- Worked with Entrepreneurs in Resident (EIR) to diligence & build new company concepts; several to term-sheet stage
- Participated in Series A, Seed financing activities across various TAs/Modalities, i.e. forecasting, terms, license negotiations
- Sourced new deal opportunities & talent for newcos via conference attendance and academic/industry relationships
- Drove several workstreams for the investment team, e.g. deal-lead for 25% of Atlas portfolio; managed deal pipeline; organized Science2Startup, founded Emerging Frontiers in Oncology

Director of Business Development & Strategy, *Compass Therapeutics* – Early Stage Biotech, Cambridge, MA **2016 – 2018**

- Interim head of Business Development, reporting directly to the CEO; input from Chair of the Board & CEO
- Developed & implemented portfolio strategies to attract strategic deals, including territory-splits and new TA entry
- Initiated a strategic academic partnership to accelerate lead asset translation and expansion of a core set of portfolio programs
- Presented BD strategy, plan, and update at Board of Directors quarterly meeting, observed other BoD meetings
- Member of the Extended Management Team; shaping the strategic, scientific, and corporate direction of the company
- Participated in strategic finance activities, including IPO considerations; geared towards bringing in dilutive funding
- Performed a variety of operational activities, e.g. in-licensing platforms, alliance management, project management, productivity database/systems, website launch

Clarion LLC – Life Science Consulting Firm, Boston, MA **2011 – 2016**

Manager/Consultant/Associate Consultant

- Led strategy projects for pipeline development, LCM, BD, commercialization, M&A for large to small cap biopharma
- Developed and pitched project proposals for several new client opportunities; most were won in competitive bids
- Co-developed Clarion's oncology business and clients
- Managed several executive-level clients at various biopharmaceutical companies and managed project teams of 5-10
- Strong focus on oncology, and worked in gene therapy, ophthalmology, I&I
- Mentored and managed Associates/Consultants

Postdoctoral Fellow, *Wistar Institute – NCI-designated Cancer Center,* Philadelphia, PA **Spring – Fall 2011**

PROFESSIONAL APPOINTMENTS

Board of Advisors – *Geisel School of Medicine at Dartmouth* **2023 – current**

Scientific Advisory Board – *Biocentury* **2022 – current**

Board of Directors – *Massachusetts Life Sciences Center* **2022 – 2024**

EDUCATION

Ph.D., Dartmouth College, Hanover, NH **2006 – 2011**

Thesis: "Immunotherapy, Diagnosis and the Immunobiology of Ovarian Cancer"

- Developed an antibody/dsRNA combination therapy for ovarian cancer in a preclinical model that provided supporting evidence for a novel combination immunotherapy being developed by a company at Dartmouth College
- Generated a novel transgenic model to define the pleotropic nature of innate cells during ovarian cancer tumorigenesis
- Investigated the dynamics of the dendritic cell migration during tumorigenesis and growth which led to a novel (patented) approach for early diagnosis of ovarian cancer using iron nanoparticles
- Initiated numerous collaborations across different disciplines, most of which resulted in peer-reviewed manuscripts
- First and co-authored thirteen scientific publications in prominent peer-reviewed journals
- Obtained independent National Institute of Health (NIH) funding in the amount of $41,176 per year

Courses for credit, Tuck School of Business at Dartmouth, Hanover, NH **2009 – 2010**

- Completed courses for credit (Healthcare and Entrepreneurship)
- Completed an on-line course in Financial Accounting

B.Sc., University of the West Indies, Kingston, Jamaica **2002 – 2005**

Major: Biotechnology, Minor: Zoology. (First-Class Honors)

SELECTED PUBLICATIONS

- Uciane Scarlett, *several articles in the* **Timmerman Report from 2020 – 2021**
- Dennis Chang, Keith Flaherty, and **Uciane K. Scarlett**. *A Tale Of Two Pipelines*, **In Vivo January 2020**
- **Uciane K. Scarlett**, Dennis Chang, Thomas Murtagh, and Keith Flaherty. *High-throughput testing of novel-novel combination therapies for cancer: an idea whose time has come*, **Cancer Discovery September 2017**
- Dennis Chang, **Uciane K. Scarlett**, Thomas Murtagh, and Keith Flaherty. *The CoNNCT Initiative: Accelerating Novel Combinations for Cancer,* **In Vivo April 2016**

ADDITIONAL INTERESTS

Culinary adventures, traveling, trekking, cycling, volunteering

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Dr Adrian Woolfson BSc (Hons), BM BCh (Oxford), PhD (Cambridge)

Curriculum Vitae (October 2024)

Name / Degrees: Dr Adrian Woolfson BSc (Hons), BM BCh (Oxford), PhD (Cambridge)

Telephone: +1 917 828 0834

Email Personal / Work: adrianwoolfson@yahoo.com
Website / Twitter: www.adrianwoolfson.com / @AdrianWoolfson

Address: , San Francisco, CA, 94111

Citizenship: US passport and UK passport

UK General Medical Council: GMC Registration (UK) Number: 4218854 (Fully registered1995 to present)

Most recent Position: Founder, Executive Chairman, and President, Replay Holdings Inc

Board Positions: Non-Executive Director ImmunoScape (Singapore/San Diego, US)
Non-Executive Director ProteinLogic (Cambridge, UK)

Scientific Advisory Boards: ImmunoScape

Editorial Boards: Editorial Board, Founding Member, Books review Editor of *GEN Biotechnology*

https://home.liebertpub.com/genbio

Education:

Balliol College, Oxford University, UK, 1992-95
(October 1st 1992 – July 7th 1995)
Gonville and Caius College, Cambridge University, UK, 1988-92
(October 1st 1988 – June 18th 1992)
University College, London University, UK, 1987-88
(October 5th 1987 – June 24th 1988)
King's College, London University, UK, 1985-87
(October 1st 1985 – June 11th 1987)

Degrees:

BM BCh Clinical Medicine (Oxford University, UK) 1995
(The BM BCh degree is the Oxford University, UK, MD equivalent)

PhD Molecular Immunology (Cambridge University, UK)
1993
(Supervised by Nobel Prize winner César Milstein)
BSc Psychology & Basic Medical Sciences (London University, UK)
1988
(1st Class, Honours)
Part II Pre-Clinical Medicine (London University, UK)
1987
(Distinction in Pharmacology)
Part I Pre-Clinical Medicine (London University, UK)
1986

Employment (Industry):

Founder, Executive Chairman, and President
2020-2024
Replay Holdings Inc, 5555 Oberlin Drive, La Jolla, CA 92121

Executive Vice President, and Head of Research and Development
2019-2020
Sangamo Therapeutics, Research and Development
501 Canal Blvd, Richmond, CA, 94804, US

Chief Medical Officer 2018
Nouscom AG, Clinical Development
Baumleingasse 18, Basel, Switzerland

Global Clinical Leader Early and Late Stage Immuno-Oncology/Hematology
2015-17 Pfizer, Global Product Development
Pfizer Employee ID: 1908801, 235 E42nd Street, New York, NY, 10017, US

Senior Medical Director, Global Clinical Lead, Oncology
2013-15
Pfizer, Clinical Development and Medical Affairs (CDMA)
Pfizer Employee ID: 1908801
235 E42nd Street, New York, NY, 10017, US

Medical Director, Global Medical Lead, Oncology 2011-13
Bristol-Myers Squibb, Discovery Medicine, Oncology
BMS Employee ID: 00194777, PO Box 4000, Princeton, NJ, 08543, US

Associate Director, Discovery Medicine and Clinical Pharmacology, Oncology
2008-11
Bristol-Myers Squibb, Discovery Medicine, Oncology
BMS Employee ID: 00194777, PO Box 4000, Princeton, NJ, 08543, US

Disease Area Specialist, Oncology 2007-08
Bristol-Myers Squibb, Medical Affairs, Oncology

BMS Employee ID: 00194777
Uxbridge Business Park, Sanderson Road, Uxbridge, UB8 1DH, UK

Employment (Internal Medicine):

Specialist Registrar (Cambridge and London)
2004-06
Internal Medicine (Neurology, Respiratory, Cardiology, Gastroenterology, Hematology)

Clinical Fellow (Cambridge) 2002-03
Internal Medicine (Neurocritical Care)

Senior House Officer (Cambridge) 2000-02
Internal Medicine (Neurology, Respiratory, Cardiology, Infectious Diseases, Intensive Care)

House Officer (Oxford and Newcastle)
1995-96 Internal Medicine and Surgery

Cambridge University PhD Studentships:

MRC Laboratory of Molecular Biology, Cambridge, UK
1989-92
University of Cambridge, Department of Zoology, Cambridge, UK
1988-89

Cambridge University Teaching Positions:

Clinical Medical Supervisor, Cambridge University MD PhD Program:

King's College, Cambridge, UK
2005-08
Gonville and Caius College, UK
2005-08
Newnham College, Cambridge, UK 2005-06
Selwyn College, Cambridge, UK
2005-06
Clare College, Cambridge, UK
2003-04
Lucy Cavendish College, Cambridge, UK
2003-04

Cambridge University Fellowships:

Charles and Katherine Darwin Research Fellow
1997-99
Darwin College, Cambridge, UK

Memberships:

Member of the Royal Society of Medicine, London, UK
2007
Member of the American Society for the Advancement of Science, US
2004-

Directorships:

Non-Executive Director ImmunoScape, San Diego, CA
2021-
(Immunomics high-dimensional immune profiling company)
Non-Executive Director ProteinLogic Ltd, Cambridge, UK
2019-
(TB diagnostics company co-founded with César Milstein)
2003-2013

Fellowships:

Honorary Clinical Fellow, Addenbrooke's Hospital, Cambridge, UK
2003-06
National Foundation for Cancer Research Fellow, Cambridge, UK
1999-00
Wellcome Trust Clinical Research Fellow, Cambridge, UK
1996-99

Electives:

Baragwanath Hospital Soweto, SA 1994
University Teaching Hospital Lusaka, Lusaka, Zambia
1994
Kaoma District Hospital, Kaoma, Zambia
1994
Children's Hospital, Harvard Medical School, Boston, US
1993

Radio and Television Interviews:

BBC Radio 4: 'In Our Time: Genetic Mutations'.
2007
With Melvyn Bragg, Professor Steve Jones and Professor Linda Partridge. Dec 06
https://www.bbc.co.uk/programmes/b008drvm

BBC Radio 4: In Business Peter Shaw takes a look at some promising British entrepreneurs. 23rd February 2006
https://www.bbc.co.uk/search?q=adrian+woolfson

BBC Radio 4: 'Should the team that cloned Dolly the sheep be allowed to work on human eggs?' Professor Christopher Shaw in conversation with Adrian Woolfson, 27th July 2004
https://www.bbc.co.uk/search?q=adrian+woolfson

BBC Knowledge. Science Fix: 'Adrian Woolfson tells Quentin Cooper how the genetic make-up of humans resembles the plans for an Airfix kit'. 01 January 2000
https://genome.ch.bbc.co.uk/940d14d072ad4eb1bfaae436a5f3742

Regulatory Interactions

Sangamo Therapeutics

FDA Regulatory Interactions:	Type B meeting, Hemophilia A (22 Jan, 2020)
	Type C meeting, MPSII (09 July, 2019)
	Type C Meeting, Hemophilia A (15 April 2019)
	Type C Meeting, Hemophilia A (30 July, 2019)
	Type C Meeting, Hemophilia A (09 Aug, 2019)
	PEI SA Meeting (05 Sept, 2019)
	Type B Meeting (22 Jan, 2019)
EU Regulatory Interactions:	PEI SA Meeting (02 Aug, 2019)
	NL SA Meeting (19 March, 2019)
	UK SA Meeting (02 May, 2019)
CTA submissions:	MPSI (22 March, 2019) UK
	MPSII Meeting (04 April 2019) UK
	Fabry (27 Sept, 2019) UK
	TX200 (16 Sept, 2019) UK
	TX200 (02 October, 2019) FR
	TX200 (04 November, 2019) NL
Regulatory Designations:	Hem A – RMAT (04 June, 2019)
	BThal – US ODD (19 Mar, 2019)
	Fabry – US ODD (21 Oct, 2019)

Pfizer and BMS

FDA Regulatory Interactions: Pre-IND meeting, Telecon: Personalized neoantigen vaccine (02 Mar, 2018)
(Presenter) Type B Meeting, in person Washington, US: *Avelumab*, 4-1BB (14 April 2016)
Type B Meeting, in person Washington, US: SMOi (22 July, 2015)
Type B Meeting, Telecon: SMOi (13 Nov, 2014)
Type B Meeting, in person Washington, US: SMOi (05 May, 2014)
Type B Meeting, Telecon: JAK2i (2012)
Pre-IND Meeting, Telecon: IGF-1R/IRi (2011)

EMA Regulatory Interactions: SAWP3 Meeting, in person London, UK: *Avelumab* (27 Sept 2016)
(Presenter) SAWP3 Meeting, in person London, UK: SMOi (02 Dec 2014)
Pre-Submission Meeting, in person London, UK: SMOi (08 Sept 2014)

Health Canada Interactions: Pre-CTA Meeting, teleconference, *Avelumab* combinations (21 Oct 2016)
(Presenter)
NICE interactions: Early Scientific Advice Meeting (in person), London, UK: *Avelumab* (02 Feb2017)
(Presenter)
MHRA interactions: Early Scientific Advice Meeting (in person), London, UK: *Personalized neoantigen*
(Presenter) *vaccination program* (28 Jun 2018)

Ph 1/2/3 Matrix team lead SMOi program (Pfizer)
Ph 1/2/3 Matrix team lead *Avelumab* I-O hem onc program (Pfizer)
Ph 1/2/3 Matrix team lead *Utomilumab* I-O hem onc program (Pfizer)

International Franchise Management

(US- and EU-based matrix team management)

Ph 1/2/3 Hematology Immuno-Oncology Early and Late Stage Leader (Pfizer)

Publications:

Scientific Papers
Available upon request

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	APPOINTMENTS TO ADVISORY COMMITTEES REQUIRING OVERSIGHT COMMITTEE APPROVAL
DATE:	FEBRUARY 11, 2025

Summary

At its February 6 meeting, the Board Governance subcommittee reviewed Presiding Officer Dr. David Cummings' proposed appointments to the Clinical Trials Advisory Committee. The subcommittee recommends that the Oversight Committee approve the three appointments. In addition, Texas Tech University System Chancellor has notified CPRIT of his appointment of Deborah Clegg, Ph.D., to the University Advisory Committee. No further action is needed.

Discussion

Texas Health & Safety Code § 102.155 allows the Oversight Committee to create ad hoc committees of experts to advise the Oversight Committee. With the exception of the University Advisory Committee, the presiding officer of the Oversight Committee is responsible for appointing experts to serve on CPRIT's advisory committees. The appointments must be approved by the Oversight Committee.

The Clinical Trials Advisory Committee (CTAC) advises the Oversight Committee on issues related to clinical trials, including providing expert opinion on the impact of current CPRIT mechanisms supporting clinical trials; highlighting opportunities to increase CPRIT's impact on translating basic discoveries to clinical trials; and advising on mechanisms that would address barriers to patient enrollment in therapeutic clinical trials.

The Board Governance subcommittee reviewed Presiding Officer Dr. Cummings' appointments to the CTAC at its February 6 meeting and voted to recommend approval to the Oversight Committee.

CPRIT CEO Kristen Doyle notified the Board Governance subcommittee of the appointment of Deborah Clegg, Ph.D., Vice President of Research at Texas Tech University Health Sciences Center El Paso to serve as the institution's representative on CPRIT's University Advisory Committee. Unlike the other CPRIT advisory committees, CPRIT's statute specifies that chancellors or presidents of the various university systems are responsible for appointing members to the University Advisory Committee. In this case, Texas Tech University System Chancellor Dr. Tedd Mitchell notified CPRIT of Dr. Clegg's appointment on December 3, 2024. No further Oversight Committee action is necessary to formalize her appointment.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Advisory Committee Appointments
February 2025

Advisory Committee	Nominee	Institution
Clinical Trials Advisory Committee	**April Bell, M.S., CCRC, ACRP, ACRP-PM** Manager, Clinical Research Operations	JPS Health Network
Clinical Trials Advisory Committee	**Everardo Cobos, M.D., FACP** Chair, Department of Medicine and Oncology	University of Texas Rio Grande Valley
Clinical Trials Advisory Committee	**Jeff Yorio, M.D.** Hematologist-Oncologist, Texas Oncology-Austin Central Central & South Texas Site Research Leader, Sarah Cannon Research Institute at Texas Oncology Chief of Hematology-Oncology, Ascension Seton Medical Center Austin	Texas Oncology

TEXAS TECH UNIVERSITY SYSTEM™

Tedd L. Mitchell, M.D.
Chancellor

December 3, 2024

Kristen Pauling Doyle, J.D.
Chief Executive Officer
Cancer Prevention & Research Institute of Texas
P.O. Box 12097
Austin, Texas 78711

Re: Nomination of Deborah Clegg, Ph.D., to the CPRIT University Advisory Committee

Dear Ms. Doyle,

I write today to nominate Deborah Clegg, Ph.D., to serve as Texas Tech University Health Sciences Center El Paso's (TTUHSC El Paso) representative on the Cancer Prevention & Research Institute of Texas (CPRIT) University Advisory Committee (UAC). Dr. Clegg has been part of the TTUHSC El Paso faculty since 2021, when she joined the Department of Internal Medicine in the Paul L. Foster School of Medicine. She is currently a professor and the university's vice president for research.

Dr. Clegg's impressive academic background includes time at Drexel University, Cedars-Sinai Medical Center and the UT Southwestern Medical Center. In 2019, she received Indiana University's Gill Transformative Investigator Award for Outstanding Contributions to Cellular, Molecular and Systems Neuroscience. She has extensive experience as a grant reviewer for organizations like the National Institutes of Health, the American Diabetes Association, Veterans Affairs and the Swiss Government Federal Foundation. Additionally, Dr. Clegg has authored or co-authored more than 200 articles in peer-reviewed, high-impact publications, including *The New England Journal of Medicine*, *JAMA*, *American Journal of Physiology* and *National Kidney Foundation*. Through her published research, Dr. Clegg has earned a spot on Stanford University's list of the world's top 2% of scientists. The list recognizes the most cited and influential scholars in their field.

In El Paso, she has helped lead efforts to increase access to health care and preventive care to reduce high rates of diabetes and cancer in the Borderplex region. She has fostered a culture of scholarly activity across the university, supporting research and scholarship and developing strategic partnerships with funding agencies and other entities.

Her dedication to serving the people of Texas, increasing access to critical health care, and identifying new initiatives to help prevent cancer and other chronic illnesses make Dr. Clegg an excellent candidate for CPRIT's UAC. I wholeheartedly endorse her for this appointment.

I appreciate your consideration. If you need any more information, please do not hesitate to contact my office.

Warmest regards,

Tedd L. Mitchell, M.D.
Chancellor, Texas Tech University System

CC: TTUHSC El Paso President Rick Lange, M.D., M.B.A.

Richard Gorlick, M.D., is division head and department chair in the Department of Pediatrics at The University of Texas MD Anderson Cancer Center. He also holds the H. Grant Taylor, M.D., W.W. Sutow, M.D., and Margaret P. Sullivan, M.D., Distinguished Chair in Pediatrics. Dr. Gorlick serves as the director of the Pediatric Sarcoma Research Laboratory, which focuses on advancing targeted therapies for childhood cancers and understanding the development and progression of osteosarcoma.

Dr. Gorlick is the PI of a CPRIT Multi-Investigator Research Awards grant (RP240440) titled **"Novel Therapies for Osteosarcoma"** which aims to reduce morbidity and mortality from pediatric osteosarcoma by developing new therapeutics for osteosarcoma.

A well-respected subject matter expert in the field of pediatric oncology, Dr. Gorlick has published over 335 peer-reviewed papers, reviews, and book chapters. He supports several organizations, including the National Cancer Institute's Pediatric Preclinical in Vivo Testing (PIVOT) Program, the Sarcoma Alliance for Research through the Collaboration Consortium, and the Children's Oncology Group (COG). Dr. Gorlick's early involvement with the COG led his laboratory to establish a bone tumor bank, which is now considered the world's largest osteosarcoma tissue bank. He is a past president of the Connective Tissue Oncology Society and is current chair of the CPRIT Advisory Committee on Childhood Cancers.

Donald (Will) Parsons M.D., Ph.D., is a board-certified pediatric oncologist, professor in the Department of Pediatrics at Baylor College of Medicine, and the Interim Director of Texas Children's Cancer and Hematology Center.

Dr. Parsons' work has been instrumental in characterizing the genetic landscapes of a variety of pediatric and adult cancers, including the first identification of IDH1 and IDH2 as critical oncogenes in gliomas. His current research primarily focuses on the clinical application of genomic technologies in pediatric cancer care.

Dr. Parsons has a particular interest in the development and evaluation of molecularly targeted therapies. He holds several leadership roles in the Houston area, including serving as the Children's Oncology Group (COG) study chair for the NCI-COG Pediatric MATCH trial (the first nationwide precision oncology trial for children with relapsed and refractory solid tumors, lymphomas, and histiocytoses), and as a Steering Committee member for the NIH Pediatric Early Phase Clinical Trials Network.

Dr. Parsons received his B.A. in chemistry from Princeton University and his M.D. and Ph.D. degrees from The Ohio State University College of Medicine. He completed his pediatric residency at Johns Hopkins University and his oncology/neuro-oncology fellowship training at Johns Hopkins and the Pediatric Oncology Branch of the National Cancer Institute. Dr. Parsons currently serves as vice chair for the CPRIT Advisory Committee on Childhood Cancers.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Advisory Committee on Childhood Cancer

Committee Annual Report

February 19, 2025

Presented By:

Richard Gorlick, M.D.

Chair, ACCC

Division Head and Department Chair, Pediatrics, The University of Texas MD Anderson Cancer Center Children's Cancer Hospital

H. Grant Taylor, M.D., W.W. Sutow, M.D., and Margaret P. Sullivan, M.D. Distinguished Chair in Pediatrics

Donald (Will) Parsons, M.D., Ph.D.,

Vice-Chair, ACCC

Professor, Pediatrics – Baylor College of Medicine

Director, Texas Children's Cancer and Hematology Center

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Children's Cancer Hospital®

Texas Children's Hospital®

Presentation Outline

- **Childhood Cancer in Texas, the US: a review**
- **Summary of CPRIT Pediatric Achievements**
- **ACCC Ongoing Steps**
  - Membership/Researchers Roundup
- **ACCC Strategy**
  - Ongoing goals
  - Vision for future
- **Summary/Next Steps**

Statement of the problem: Childhood Cancer

Childhood Cancer: A Texas-sized problem?

- Texas has the **second highest cancer population** in the United States
- **Cancer is still the leading cause of disease-related death in Texas** past infancy among children* and adolescents**
- In Texas, the age-adjusted incidence rate for children*** hovers around 16.5 cases per 100,000 population
  - within the national average
- **In Texas, over 1,800 children per year under age 20** are diagnosed with cancer+
- Each year, **~ 7,800 Adolescents and Young Adult (AYA) are diagnosed with cancer in Texas**

*birth to 14 years ** 15-19 years old *** birth to 19 years

+Calculated as Texans diagnosed with childhood and adolescent cancer between 1995–2019 who were alive as of January 1, 2020).

An Investment in Our Future…

- The number of children in Texas is projected to **increase to over 8.5 million by 2060**
  - Investing in childhood cancer research and prevention is an investment in our future
- According to the U.S. Census Bureau, **Texas is the second youngest state in the nation** (35 = median age)
- The population of Texas children under age six is greater than OK, LA, FL and NM **combined**
  - Approximately 1 in 10 American children under age six live in TX

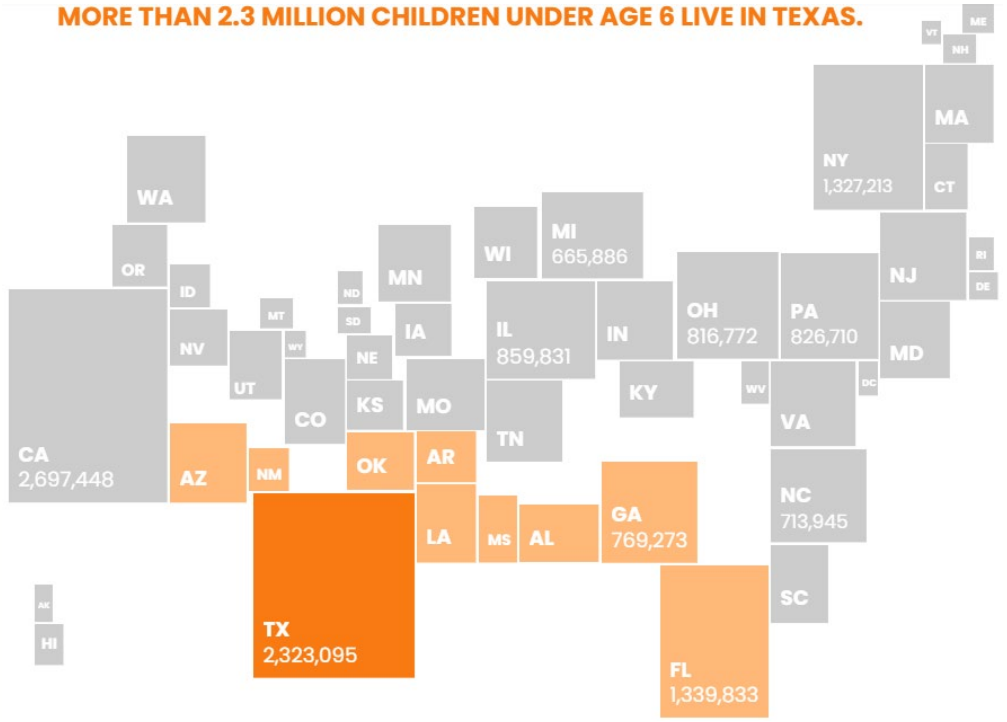


Image retrieved from TexasReadyKids website (2025)

Adolescent & Young Adult Cancer (AYA)

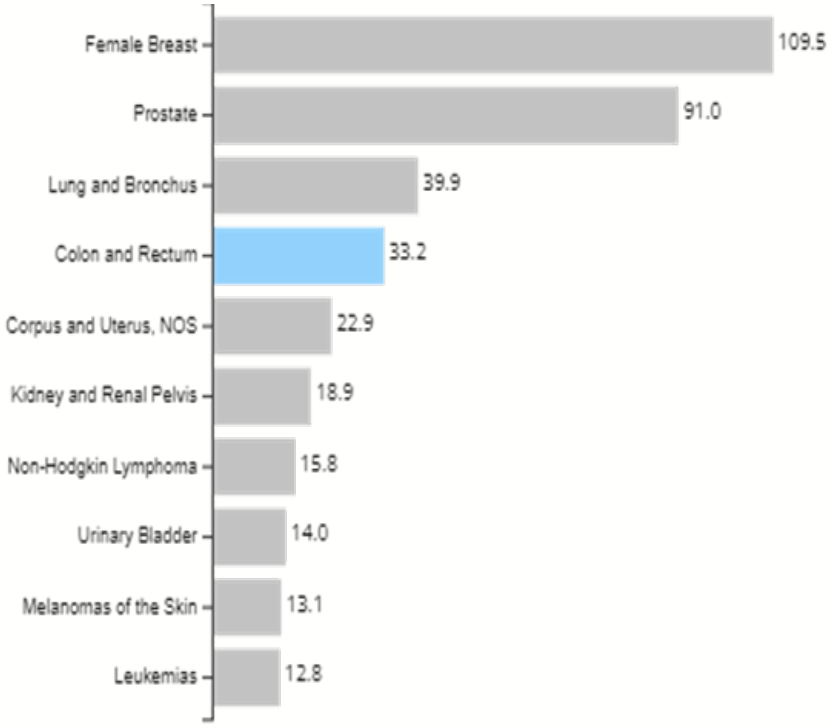
- The National Cancer Institute defines the AYA age range as 15-39

- The five-year overall survival for AYA is 85.9%, limited improvement in cure rates for many AYA diagnoses
  - **sarcoma**, CNS tumors, **early onset colorectal cancer,** breast cancer

- **Colorectal cancer (CRC) rates on the rise** for individuals under 50
  - In 2023: 19,550 cases and 3,750 deaths in individuals younger than 50 years of age

- There are few studies focused on AYA short and long-term survival and quality of life
  - 100,000+ childhood and AYA survivors live in Texas

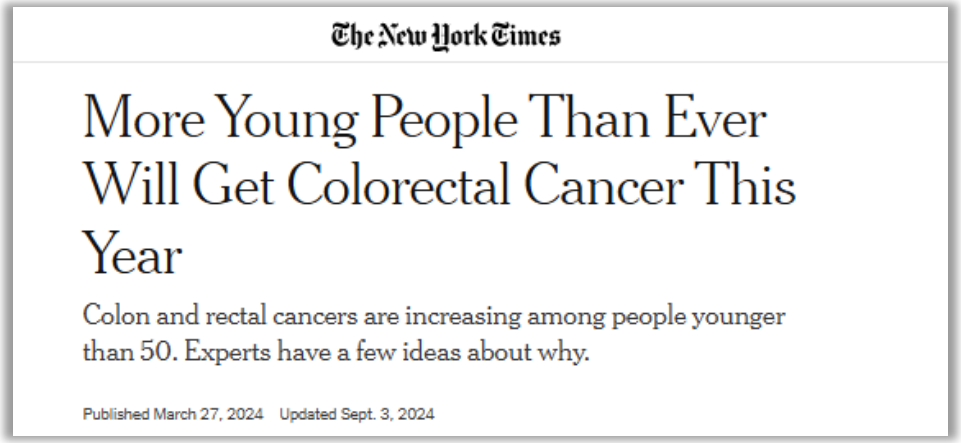
Top 10 Cancers by Rates of New Cancer Cases
Texas, 2020*



*All Races, Ages, & Ethnicities, Male and Female

Cancer Among Adolescents and Young Adults (AYAs) — Cancer Stat Facts

The incidence of cancer in AYAs is increasing



The New York Times

More Young People Than Ever Will Get Colorectal Cancer This Year

Colon and rectal cancers are increasing among people younger than 50. Experts have a few ideas about why.

Published March 27, 2024 Updated Sept. 3, 2024

The ASCO Post

AYAs Enrolled in a Cancer Program Were More Likely to Receive Guideline-Recommended Care

By Jo Cavallo

October 10, 2024

THE WALL STREET JOURNAL.

HEALTH | HEALTHCARE

Younger Women Are Now More At-Risk for Cancer Than Men

Trends in breast, prostate and lung cancer are shifting who is most at-risk

By Brianna Abbott Follow

Jan. 16, 2025 8:00 am ET

Medscape Tuesday, February 13, 2024

COMMENTARY

More Young Women Being Diagnosed With Breast Cancer Than Ever Before

JAMA Network

January 26, 2024

Breast Cancer Incidence Among US Women Aged 20 to 49 Years by Race, Stage, and Hormone Receptor Status

Shuai Xu, MPH[1]; Sara Murtagh, MD[2]; Yunan Han, MD[1]; et al

Author Affiliations | Article Information

JAMA Netw Open. 2024;7(1):e2353331. doi:10.1001/jamanetworkopen.2023.53331

Summary of CPRIT Pediatric Accomplishments

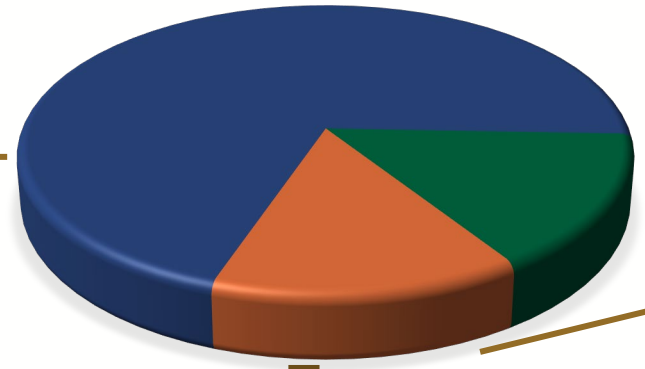
Fighting Childhood & Adolescent Cancer in Texas

- **1936** Texas children and adolescents diagnosed in 2023; **230** died
- **2nd** highest percentage of cases in the nation **(10%)**
- #3 in the nation for Leukemia, #5 in all cancer types

Texas has unique disparities due to geographic, socioeconomic, and cultural diversity. Cancer incidence and 5-yr survival worse (below state average) in border & rural areas.

- CPRIT has Invested more than $474 million dollars in research on childhood and adolescent cancers - **13% of entire portfolio**
- Our commitment to childhood cancer research is **proportionally 3X the national commitment**
- Launched **196 research projects focused on childhood cancers and 22 Cores,** 490 scientific publications, 38 patents filed
- Funded **50 clinical trials or studies, impacting over 16,000 patients**
- **Brain Cancer: >$46 M**
- **Leukemia: >$340 M**
- **Ewing's Sarcoma: >$20 M**

CPRIT Has Invested $476.5 M in Cancer in Children and Adolescents

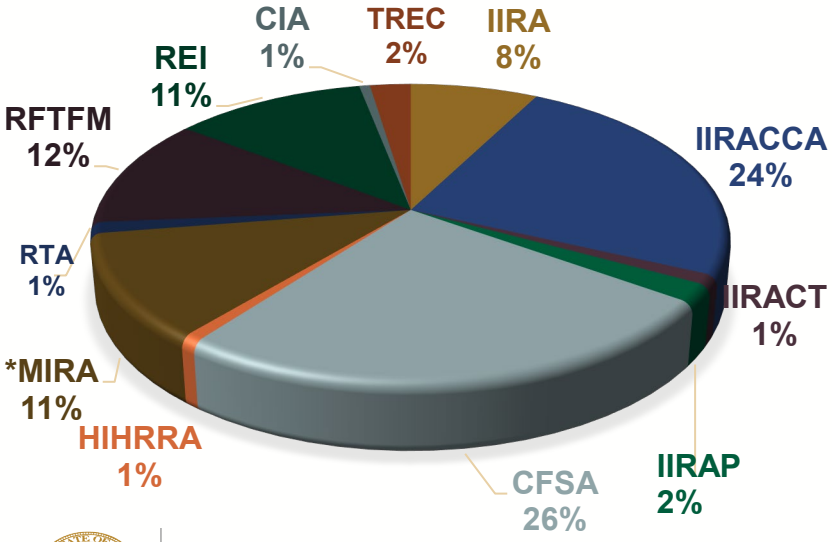


Academic Research
$333.6 M, 196 awards

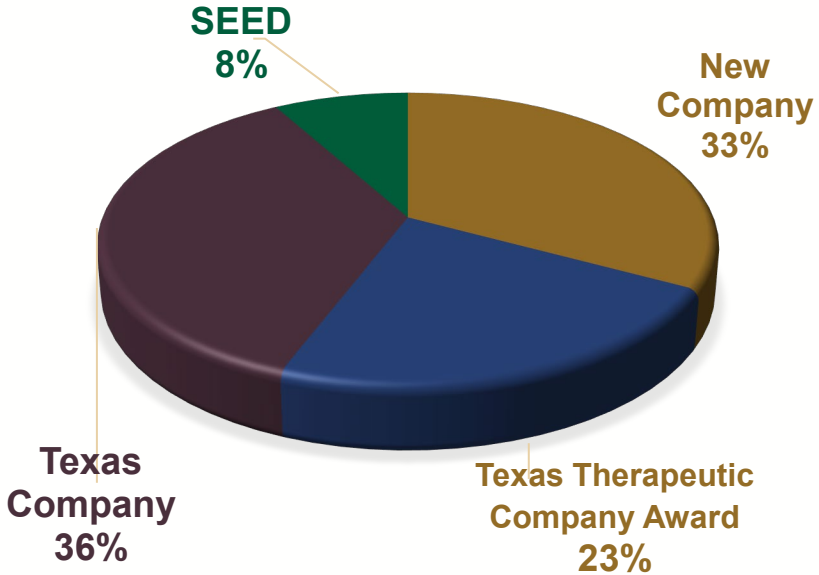
Prevention
$68.6 M, 47 awards

Product Development
$72.3 M, 8 awards

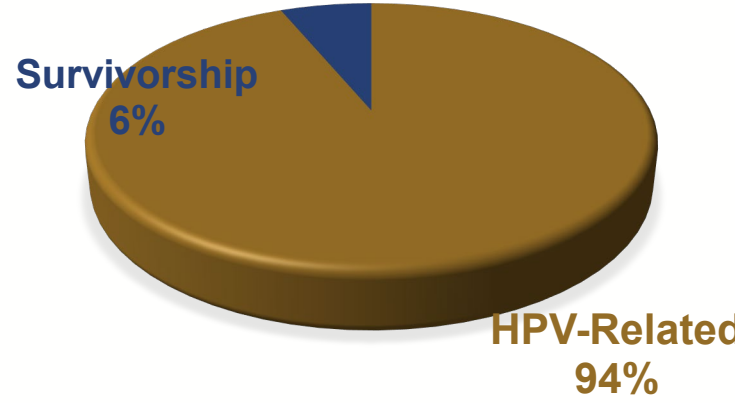
Academic Research $333.6 M (196)



Product Development, $72.3 M (8)



Prevention $68.6 M (47)



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CPRIT Supports Recruitment of Childhood Cancer Researchers

Mechanism	# Awards	Funding
Recruitment of Established Investigators	6	$38,177,801
Recruitment of First-Time, Tenure Track Faculty Members	20	$39,400,000
Total	**26**	$77,577,801

Michael D. Taylor, MD, PhD
Professor and Director,
Pediatric Neurooncology Research
Texas Children's Hospital, BCM

- Dr. Michael Taylor - a pediatric neurosurgeon - was successfully recruited from the University of Toronto with support from a CPRIT Established Investigator Scholar Award.
- Dr. Taylor's research has revolutionized the classification of childhood brain tumors, prompting the WHO to adopt a molecular classification for medulloblastoma and ependymoma employed internationally.
- In Texas, he is continuing to refine our understanding of brain tumor biology and genetics, and to test novel epigenetic and immunotherapeutic strategies.

Core Facilities Support Awards (N=22)

Provides financial support for a wide variety of projects relevant to cancer research in Texas, including for pediatric specific projects such as:

Title	PI	Institution	Award Year
Children's Research Institute Metabolomics Core: Advanced Methodologies in Cancer Metabolism	Ralph DeBerardinis, MD, PhD	The University of Texas Southwestern Medical Center	2024
Pediatric Cancer Data Core	Yang Xie, PhD	The University of Texas Southwestern Medical Center	2024
Renewal of CPRIT GMP Core	Natalia Lapteva, PhD	Baylor College of Medicine	2024
Texas Pediatric Cancer Testing (TPCT) Core	Peter Houghton, PhD	The University of Texas Health Science Center at San Antonio	2022
West Texas Pharmacology Core	Min Kang, PharmD	Texas Tech University Health Sciences Center	2022

Multiple-Investigator Research Awards (N=36)

Support highly integrated programs of collaborative and cross disciplinary research:

Title	PI	Institution	Award Year
Novel Therapies for Osteosarcoma	Richard Gorlick, MD	The University of Texas M. D. Anderson Cancer Center	2024
Neural Regulation of Childhood Cancers	Sean Morrison, PhD	The University of Texas Southwestern Medical Center	2024
Cellular Immunotherapies for Pediatric Solid Tumors	Leonid Metelitsa, MD, PhD	Baylor College of Medicine	2024
Predictive biomarkers and novel therapies for high-risk pediatric liver cancers	Dolores López-Terrada, MD, PhD	Baylor College of Medicine	2018

Impact of CPRIT Funding Mechanisms

- **Impact**
  - Over 200 awards, $661M+ follow-on funds, 794 publications, 40 patents filed, 47 clinical trials with 12,000+ patients enrolled
  - **New, shareable childhood cancer models**
    - Texas Pediatric PDX facility (Houghton, UTHSCSA)
    - PDX-AIM (Lewis, BCM)
    - Cancer Animal Facility (Trasti, TTUHSC)
  - **New capacity for data storage and sharing**
    - Pediatric Cancer Data Core (Xie, UTSW)
    - Pediatric Solid Tumors Comprehensive Data Core (Gorlick, UTMDACC)
    - ACCESS for Texas (Scheurer, BCM)
- **Recommendations**
  - **Specific calls for proposals focused on childhood cancer**
    - Ensure impact extends beyond local institutions
    - Enlist ACCC to help prioritize Core Facilities
    - Invite competitive renewal of high-performing Cores that fill state-wide needs

CPRIT Funds Important Childhood Cancer Research: FY24

- New individual research projects tackling big problems
  - **Impact of Germline Variants on Pediatric Leukemia Progression**- Yu Luan, Ph.D., University of Texas Health Science Center at San Antonio
  - **Advancing Immunotherapy for high-risk cancers**- Meenakshi Hegde, MD, Baylor College of Medicine
  - **Signal-Augmented Cancer Cell Therapies**- Bilal Omer, MD, Baylor College of Medicine
  - **In vivo chimeric antigen receptor macrophages for diffuse midline glioma**- Wen Jiang, MD, PhD, The University of Texas M.D. Anderson Cancer Center
  - **Myeloproliferative neoplasms**- Radek Skoda, MD, Baylor College of Medicine
  - **Overcoming transcriptional dysregulation**- Richard Voit, MD, PhD, The University of Texas Southwestern Medical Center
  - **Chromatin regulators in cancer plasticity**- Claudia Yun Wei, PhD, The University of Texas Southwestern Medical Center

Big and Bright: Texas is Leading the Nation

- National Cancer Institute – Children's Oncology Group Pediatric MATCH trial
  - **Will Parsons,** M.D., Ph.D. – BCM/Texas Children's Hospital

- Pediatric Preclinical in Vivo Testing (PIVOT) program contributions
  - **Richard Gorlick**, M.D., UTMDACC: osteosarcoma
  - **Peter Houghton,** Ph.D.& **Raushan Kurmasheva,** Ph.D., – UT Health San Antonio
    - Ewing Sarcoma, rhabdomyosarcoma, kidney and liver cancers

- Childhood Cancer Data Initiative contributions
  - **Maria Gramatges,** M.D., Ph.D. & **Will Parsons,** M.D., Ph.D. – BCM/Texas Children's Hospital
  - **Gail E. Tomlinson**, M.D., Ph.D.; **Yidong Chen,** Ph.D.& **Greg Aune,** M.D, Ph.D. – UT Health San Antonio

- Osteosarcoma Specimen Bank - **Richard Gorlick,** M.D., UTMDACC

- Adolescent and Young Adult Program:
  - UTMDACC leads the largest and most comprehensive program in the nation- **Michael Roth**, M.D.

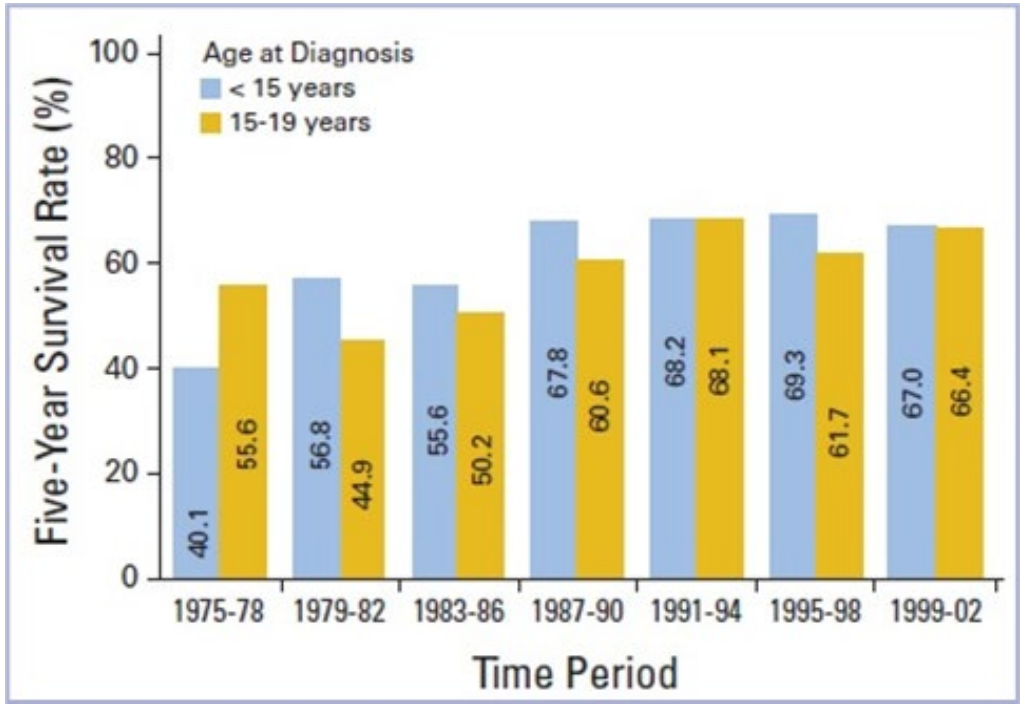
Reinstated opportunities

- **A Core Facilities Support Award Call for Applications** occurred in 2024
  - 22 applications submitted, 9 funded
- **An RFA R-24.2-MIRA was reinstated**
  - Award: Up to $4.5 Million over a period of four years
  - This reinstatement allowed for two applications from each institution
    - One for anything, one for pediatrics or population
    - 18 applications submitted, 5 funded
- **An RFA R-25.2-TREC CFSA was created**
  - Award: Up to $2 Million over a period of five years

Progress remains to be needed, in many areas

- New, effective, non-cytotoxic drugs are still needed to make progress in Sarcoma
- The INT0133 and EURAMOS studies failed to change the standard of care in North America
  - Refers to additional trials of cytotoxic chemotherapy but also has implications for needed level of evidence
- No progress has been made in improving the survival of osteosarcoma in the past 30 years

Smith, et al. Outcomes for children and adolescents with cancer. J Clin Oncol 2010.



Advisory Committee on Childhood Cancer
Ongoing Steps

CPRIT ACCC Organization

We continue to add new members to expand our network!

Leadership
Richard Gorlick, M.D., Chair
Donald (Will) Parsons, M.D., Ph.D., Vice Chair

Members
Karen Albritton, M.D.; Carl E. Allen, M.D.; Mohamad Al-Rahawan, M.D., MPH; Greg Aune, M.D., Ph.D., F.A.A.P.; Juan Carlos Bernini, M.D.; Smita Bhaskaran, M.D.; Tim Culliver; Barkat Hooda, M.D.; Eugenie Kleinerman, M.D.; Andrew Y Koh, M.D.; Annette Leslie; Julie Luke, C.P.N.P.; Phillip Neff, M.D.; C Patrick Reynolds, M.D., Ph.D.; Lisa Tichenor; Gail Tomlinson, M.D., Ph.D.; Atul Varadhachary, M.D., Ph.D,; Amir Mian, MD, M.B.A.; Virginia Harrod, M.D.

SC1: AYA
Karen Albritton (Leader), Michael Roth, Chibuzo O'Suoji (Members)

SC2: Brain Tumors
Donald Parsons (Leader), Daniel Bowers, Holly Lindsay (Members)

SC3: Cell Therapy
Andrew Koh (Leader), Kris Mahadeo, Robin Parihar, Samuel John, Matthew Campbell, Meena Hegde (Members)

SC4: Epidemiology
Philip Lupo (Leader), Paul Scheet, Sandi Pruitt, Michael Scheurer, Michael Roth (Members)

SC5: Frontiers
Smita Bhaskaran, Mohamad Al-Rahawan, (Leader), Lisa Thicenor, Shannon Cohn (Members), Richard Gorlick (Advisor)

SC6: Genetic Predisposition & Risk
Gail Tomlinson (Leader), Laura Klesse (Member)

SC7: Leukemia / Lymphoma
Carl Allen (Leader), Rachel Rau (Member)

SC8: Solid Tumors
Nino Rainusso (Leader), Jessica Naiditch, Dinesh Rakheja, Gabriel Axelrud, Lorimar Ramirez (Members)

SC9: Survivorship
Greg Aune (Leader), Barbara Jones, Monica Gramatges, Chibuzo O'Suoji, Michael Roth (Members)

Welcome, Dr. Amir Mian!

- Dr. Mian is the Arthur H. Dilly Endowed Chair in Pediatric Oncology, Professor of Pediatrics, and Division Chief of Pediatric Hematology Oncology at Dell Children's Medical Center, University of Texas at Austin.
  - Additional training in Clinical Informatics/Data Analytics, Clinical Epidemiology/Research Methods, and MBA-HealthCare (Business of Medicine).
  - Clinical interests include Leukemia/Lymphoma supportive care and Health Care Economics
  - Research interests include predictive model building.
  - Focus on Quality Improvement using Machine Learning to improve patient outcomes.
- <u>Key Leadership Roles:</u>
  - Board of Trustees, ASPHO (2024-2027)
  - Vice Chair, Finance Committee, ASTCT (2023-2025)
  - Past Chair, Practice Committee, ASPHO (2020-2024)
  - Founding Member and Member and Past Chair of Innovation, Informatics and Entrepreneurship (IIE-SIG), ASPHO (2020-2023)

ACCC Recommendations to CPRIT – Ongoing steps

- Enhanced website for Core information dissemination
- Patient Derived Xenograft sharing/ homogenization
- Texas-wide Infra-structure for Pediatric Cancer Research
- Multi-Investigator Awards (MIRAs)
- Data harmonization and sharing
- Integrated Model Sharing/Pre-clinical testing/Product Devel.
- Expanded opportunities to develop Cores
- Recruitment in areas or disciplines with gaps/opportunities
- Vaccinate all Texans 9-26 against HPV-associated cancers

Support funding mechanisms which would accrue patients throughout Texas

						
Enhance drug development in the state of Texas	Study sub-groups	Continue to grow membership of advisory council to increase collaboration	Provide interventions	Expand reach via technology	Include underserved populations	Provide services not often available outside large academic centers

Researchers Roundup 2024 – Opportunity to develop and refine strategy – Many thanks to the Carson Leslie Foundation and CPRIT for their engagement

Researcher Roundup - Dallas, TX

Members of the ACCC convened in Dallas on November 10, 2024

The charge:

Define an RFA that will address a key issue in the state of Texas for childhood cancer.

- **Session A: AYA/ Survivorship/ Health Disparities**
  - The group discussed the current state of AYA cancer survivors in Texas, potential interventions
- **Session B: Pharmaceutical Industry/Drug Development/Health Disparities/Clinical Trials**
  - gather baseline data on patients diagnosed and treatment
  - assess if patients receive appropriate standard of care
  - determine participation rates in registries and clinical trials.

Advisory Committee on Childhood Cancer: Recommendations/Strategy

ACCC Recommendations to CPRIT

- Critical to continue Pediatric Applications particularly MIRAs and Core Grants but also research grants and Recruitment Awards
- Continued immediate opportunities:
  - Enhanced website for Core information dissemination
  - Model sharing with treatment development structure
  - Data harmonization/sharing
  - Enhanced ability to participate in Cores as well as encouragement of utilization
  - Prepare manuscript describing ACCC strategy and outcomes for publication in a scientific journal

ACCC Recommendations to CPRIT

- Longer-Term opportunities:

Multi-Investigator Research Award (MIRA) in Cancer Care Delivery components

- Defines population at risk and interventions received
- Supports access to services in remote regions of the state, vulnerable populations
- Remote enrollment with centralized data collection and service delivery
- Must be available as a shared resource for investigation
- Projects must include assessments of efficacy, feasibility, acceptability, impact on health outcomes
- Must include an implementation scientist/data scientist
- Must include a patient advocate, community advisor
- Priority given to projects that promote multiple lines of referral (self, PCP, community or cancer center oncologist)
- Use digital health technology, telehealth, mobile care delivery
- Establish collaborations with community providers
- Include patient-reported outcomes
- SDOH-targeted interventions (grocery/transportation, resource navigation to WIC, SNAP)

ACCC Recommendations to CPRIT

- Longer-Term opportunities:

Multi-Investigator Research Award (MIRA) in Cancer Care Delivery - examples

- Clinical treatment trials
- Fertility preservation
- Patient/caregiver psychosocial support and mental health services
- Survivorship services (e.g., local labs and screening)
- Genetic predisposition counseling and testing
- Activity interventions/CVD risk reduction
- SDOH-targeted interventions (grocery/transportation, resource navigation to WIC, SNAP)

Many thanks to CPRIT Leadership

- Incredible engagement in issues facing children with cancer
  - Michelle Le Beau
  - Kristen Doyle
  - David A. Cummings
  - Patty Moore
  - Myriam Casillas

Summary

- The ACCC wants to extend their appreciation to Texans for their strategic development of CPRIT
- CPRIT has allowed remarkable innovation and scientific breakthroughs to occur, benefitting children with cancer in Texas.
- Thank you for supporting the visionary leadership that continues to move the needle for childhood cancer research!
- Continued support of pediatric-focused proposals remains critical

Q&A

Richard Gorlick, M.D.
Chair, CPRIT Advisory Committee on Childhood Cancers

Will Parsons, M.D., Ph.D.
Vice Chair, CPRIT Advisory Committee on Childhood Cancers

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	JOHN ELLIS, GENERAL COUNSEL CAMERON L. ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	CHAPTER 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION
DATE:	FEBRUARY 10, 2025

Summary and Recommendation

The Board Governance Subcommittee convened on February 6 to review the final order adopting rule amendments to Chapter 703. The subcommittee voted to recommend that the Oversight Committee approve adoption of the rule changes. Once the Oversight Committee approves the final order adopting the rule changes, CPRIT will submit the amendment to the Secretary of State and the change will be effective 20 days later.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy. CPRIT did not receive any public comments after the Secretary of State published the proposed amendments in the December 6, 2024, edition of the *Texas Register*.

The Board Governance Subcommittee met on February 6 to discuss the proposed adoption of the following rule amendments with CPRIT staff.

First, the amendment to § 703.13(b) increases the grant recipient audit threshold from $750,000 to $1 million. Grantees who receive state funds in an amount at or above the threshold must obtain an audit and provide it to CPRIT. CPRIT follows the threshold set in the Texas Grant Management Standards (TxGMS), published by the Comptroller's Office. The Comptroller released a new version of TxGMS on October 1st, increasing the audit threshold to $1 million.

Next, the proposed change to § 703.26(b) replaces an outdated reference to the Uniform Grant Management Standards (UGMS) with TxGMS. After TxGMS went into effect, CPRIT amended its rules to replace references to UGMS with TxGMS. This non-substantive change corrects a reference that was previously overlooked.

Finally, the amendment to § 703.26(e) adds to the list of unallowable grantee expenses, "Reimbursements to employees for their out-of-pocket health insurance premium or other health care expenses which are not made through an employer-sponsored plan established under

Section 105 of the Internal Revenue Code." This clarifies that CPRIT practices follow current laws and regulations governing these expenses.

The subcommittee voted to recommend that the Oversight Committee approve the rule amendments for final adoption.

Next Steps

After the Oversight Committee adopts the proposed rule change, CPRIT will submit the final order to the Secretary of State. The rule change will become effective 20 days after the date CPRIT files the order with the Secretary of State.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to 25 Tex. Admin. Code §§ 703.13(b) and 703.26 without changes to the proposed amendments as published in the December 6, 2024, issue of the *Texas Register* (49 TexReg 9888); therefore, the rules will not be republished.

Reasoned Justification

The amendment to § 703.13(b) increases the grant recipient audit threshold from $750,000 to $1 million. The amendment harmonizes CPRIT's administrative rules with recent changes to the Texas Grant Management Standards (TxGMS) published by the Comptroller of Public Accounts.

The amendment to § 703.26(e) adds the following as an unallowable expense for grant recipients, "Reimbursements to employees for their out-of-pocket health insurance premium or other health care expenses which are not made through an employer-sponsored plan established under Section 105 of the Internal Revenue Code." For these expenses to be considered fringe benefits that are reimbursable from CPRIT grant funds, the employer must have an established health reimbursement arrangement program under Section 105 of the Internal Revenue Code. Thus, this amendment clarifies that CPRIT program standards for reimbursements conform to other relevant laws.

Lastly, the non-substantive, technical amendment to § 703.26(b) replaces an outdated reference to the Uniform Grant Management Standards (UGMS) with a reference to TxGMS.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to §§ 703.13 and 703.26. CPRIT staff recommends moving forward with adoption of the amendments.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that John Ellis, General Counsel for CPRIT, reviewed the adoption of the rules and found it to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on February 21, 2025.

<rule>

§703.13.Audits and Investigations.

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the

Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(1) A Grant Recipient shall maintain its records pertaining to the specific Grant Contract for a period of three years following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(2) The Grant Recipient may maintain its records in either electronic or paper format.

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended $1 million or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $1 million or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e) of this section.

(1) The audited time period is the Grant Recipient's fiscal year.

(2) The audit must be submitted to the Institute within thirty (30) days of receipt by the Grant Recipient but no later than nine (9) months following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than nine (9) months following the close of the Grant Recipient's fiscal year.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds

during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(e) For purposes of this rule, an agreed upon procedures engagement is one in which an independent certified public accountant is hired by the Grant Recipient to issue a report of findings based on specific procedures to be performed on a subject matter.

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or for-profit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office.

(2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

(3) The certified public accountant is to perform procedures prescribed by the Institute and to report his or her findings attesting to whether the Grant Recipient records are in agreement with stated criteria.

(4) The agreed upon procedures apply to all current year expenditures for Grant Awards received by the Grant Recipient. Nothing herein prohibits the use of a statistical sample consistent with the American Institute of Certified Public Accountants' guidance regarding government auditing standards and 2 CFR Part 200, Subpart F, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

(5) At a minimum, the agreed upon procedures report should address:

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

(E) Grant Award expenditures (payroll and non-payroll related transactions);

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

(6) The certified public accountant should consider the specific Grant Mechanism and update or modify the procedures accordingly to meet the requirements of each Grant Award and the Grant Contract reviewed.

(f) For purposes of this rule, a program specific audit should address:

(1) Sample of awards;

(2) Reporting;

(3) Indirect costs;

(4) Matching funds, if appropriate;

(5) Expenditures;

(6) Expenditure Reporting;

(7) Personnel Level of Effort Reporting;

(8) Grant Closeout;

(9) Performance Measures;

(10) Publications and Acknowledgements;

(11) Title to equipment;

(12) Contract certifications;

(13) Changes in Principal Investigator or Program Director;

(14) Intellectual Property and revenue sharing;

(15) Early termination and event of default; and

(16) Any other issue identified by the Institute, the Grant Recipient, or the person performing the program specific audit.

(g) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.26.Allowable Costs.

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24 of this title (relating to Financial Status Reports).

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the Texas Grant Management Standards (TxGMS) adopted by the Comptroller's Office. If guidance from TxGMS on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from the Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(7) An honorary gift or a gratuitous payment.

(8) Interest and other financial costs related to borrowing and the cost of financing.

(9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(10) Liability insurance coverage.

(11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(12) Professional association fees or dues for an individual employed by the Grant Recipient. Professional association fees or dues for the Grant Recipient's membership in business, technical, and professional organizations may be allowed, with prior approval from the Institute, if:

(A) the professional association is not involved in lobbying efforts; and

(B) the Grant Recipient demonstrates how membership in the professional association benefits the Grant Award project(s).

(13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(14) Fees for visa services.

(15) Payments to a subcontractor if the subcontractor working on a Grant Award project employs an individual who is a Relative of the Principal Investigator, Program Director, Company Representative, Authorized Signing Official, or any person designated as Key Personnel for the same Grant Award project (collectively referred to as "affected Relative"), and the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary or the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.

(A) For exceptional circumstances, the Institute's Chief Executive Office may grant an exception to allow payment of Grant Award funds if the Grant Recipient notifies the Institute prior to finalizing the subcontract. The Chief Executive Officer must notify the Oversight Committee in writing of the decision to allow reimbursement for the otherwise unallowable expense.

(B) Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(16) Fundraising.

(17) Tips or gratuities.

(18) Reimbursements to employees for their out-of-pocket health insurance premium or other health care expenses which are not made through an employer-sponsored plan established under Section 105 of the Internal Revenue Code.

(f) Pursuant to Texas Health and Safety Code Section 102.203(b) the Institute may authorize reimbursement for one or more of the following expenses incurred by a cancer clinical trial participant that are associated with participating in a clinical trial and included in the Grant Recipient's Approved Budget:

(1) transportation, including car mileage, parking, bus fare, taxi or ride hailing fare exclusive of tips, and commercial economy class airfare within the borders of the State of Texas;

(2) lodging; and

(3) any cost reimbursed under a cancer clinical trial participation program established pursuant to Texas Health and Safety Code Chapter 51 (relating to Cancer Clinical Trial Participation Program).

(g) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: GRANT WEAVER, CHIEF FINANCIAL OFFICER

SUBJECT: CHIEF FINANCIAL OFFICER REPORT

DATE: FEBRUARY 11, 2025

CPRIT Financial Overview for FY 2025, Quarter 1

FY 2025, Quarter 1 Operating Budget

CPRIT has an appropriated budget of $5.0 million in Indirect Administration and approximately $16.4 million in Grant Review and Award Operations. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts which support grant award and administration, including the $9.7 million contract for grant management support services with GDIT.

Approximately 72 percent of the approximate $5.0 million budget for Indirect Administration had been encumbered or expended. Grant Review and Award Operations includes a planned transfer of approximately $1.3 million from Award Cancer Research Grants to cover the costs associated with contract staff to augment grant accounting and compliance staff, increased peer review honoraria, and the ongoing expense for the grant management support contract, bringing the operating budget to approximately $17.7 million. Of this $17.7 million budget for Grant Review and Award Operations, approximately 69 percent had been encumbered or is expended.

CPRIT received approximately $230,366 in revenue sharing payments during the first quarter. This amount includes the receipt of a quarterly royalty payment for $204,836 from Merck & Co., Inc. from the sales revenue of WELIREG™ (belzutifan).

Revenue sharing payment deposits from CPRIT's inception total approximately $10.9 million through the end of January 2025.

FY 2025, Quarter 1 Performance Measure Report

In the first quarter, CPRIT reported to the Legislative Budget Board a total of 230,046 people served through CPRIT prevention and control grants and no company relocations.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $69.5 million in commercial paper notes on CPRIT's behalf in December 2024. This was the second tranche of issuances against the $298.1 million projected to be issued in FY 2025.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of November 30, 2024

Indirect Administration (B.1.1.)

		2025 Appropriated	2025 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,940,880	$ 1,845,652		$ 496,450	1,349,202	27%	$ 496,450	$ 1,349,202
1002	Other Personnel Costs	38,785	38,785		5,806	32,979	15%	5,806	32,979
2001	Professional Fees and Services	1,808,662	1,748,341		1,266,753	481,588	72%	1,266,753	481,588
2003	Consumable Supplies	24,000	24,000		1,331	22,669	6%	1,331	22,669
2004	Utilities	58,600	58,600		36,750	21,850	63%	36,750	21,850
2005	Travel	45,000	45,000		11,617	33,383	26%	11,617	33,383
2006	Rent-Building	11,000	11,000		2,431	8,569	0%	2,431	8,569
2007	Rent-Machine and Other	32,172	32,172		9,000	23,172	28%	9,000	23,172
2009	Other Operating Expenses	1,045,249	1,200,798		1,766,154	(565,355)	147%	1,766,154	(565,355)
	Subtotal - Indirect Administration (B.1.1.)	**$ 5,004,348**	**$ 5,004,348**	**1.69%**	**$ 3,596,294**	**$ 1,408,054**	**72%**	**$ 3,596,294**	**$ 1,408,054**

Grant Review and Award Operations (A.1.3.)

		2025 Appropriated	2025 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 3,786,237	4,673,532		$ 1,205,999	$ 3,467,533	26%	$ 1,205,999	$ 3,467,533
1002	Other Personnel Costs	45,000	45,000		13,129	31,871	0%	13,129	31,871
2001	Professional Fees and Services	12,419,373	12,883,652		11,058,880	1,824,772	86%	11,058,880	1,824,772
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	12,000		-	12,000	0%	-	12,000
2005	Travel	45,000	45,000		15,033	29,967	33%	15,033	29,967
2009	Other Operating Expenses	71,649	71,374		10,607	60,767	15%	10,607	60,767
	Subtotal - Grant Operations (A.1.3.)	**$ 16,379,259**	**$ 17,730,558**	**6.00%**	**$ 12,303,647**	**$ 5,426,911**	**69%**	**$ 12,303,647**	**$ 5,426,911**

Grants

		2025 Appropriated	2025 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 27,297,961	$ 27,361,598		$ 27,361,598	$ 0	100%	$ 27,361,598	$ 0
4000	Grants - Research (A.1.1.)	248,251,400	$ 245,347,226		245,347,226	$ -	100%	245,347,226	-
	Subtotal - Grants	**$ 275,549,361**	**$ 272,708,824**	**92.30%**	**$ 272,708,824**	**$ 0**	**100%**	**$ 272,708,824**	**$ 0**
	Grand Totals	**$ 296,932,968**	**$ 295,443,730**	**100.00%**	**$ 288,608,765**	**$ 6,834,965**	**98%**	**$ 288,608,765**	**$ 6,834,965**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of November 30, 2024

	11/01/2024-11/30/2024	AY 25 Year to Date as of 11/30/2024
Beginning Balance : 9/01/2024		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance: 11/30/2024		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of November 30, 2024

		11/01/2024-11/30/2024	AY 25 Year to Date as of 11/30/2024
Beginning Balance : 9/01/2024			**$ 63,637.46**
Increases:			
(1)	License Plate Revenue Received	$ 353.83	$ 1,395.15
	Interest	$ 169.98	$ 518.28
Total Increases		**$ 523.81**	**$ 65,550.89**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		-	-
Total Reductions		**$ -**	**$ -**
Ending Balance: 11/30/2024			**$ 65,550.89**

Note:

Balance forward from 2024 License Plate $63,637.46

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of November 30, 2024

		11/01/2024-11/30/2024	AY 25 Year to Date as of 11/30/2024
Beginning Balance : 9/01/2024			**$ 30,306.75**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ -
(2)	Conference Registration Fees	$ -	$ -
(3)	Conference Registration Fees-Credit Card	$ -	$ -
Total Increases		**$ -**	**$ -**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ -	$ -
	Refund-Application Fees	$ -	$ -
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 11/30/2024			**$ 30,306.75**

Forward balance for FY 2024 is $0.00

Application Fees

Conference Fee for FY 2024 is $30,306.75

Cancer Prevention and Research Institute of Texas

Interest & Sinking Fund Account - 5168

As of November 30, 2024

		11/01/2024-11/30/2024	AY 25 Year to Date as of 11/30/2024
Beginning Balance : 9/01/2024			**$ 7,233,054.13**
Increases:			
(1)	Revenue Sharing / Royalties	$ 217,852.93	$ 227,353.80
		$ -	$ -
Total Increases		**$ 217,852.93**	**$ 7,460,407.93**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 11/30/2024			**$ 7,460,407.93**

Balance forward from FY 2024 is $7,233,054.13

Cancer Prevention and Research Institute of Texas
FY 2025, Quarter 1 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	750,000	230,046	0	0	0	230,046	30.67%
Number of Entities Relocating to TX for Cancer Research Related Projects	3	0	-	-	-	0	0.00%
Annual Age-adjusted Cancer Mortality Rate	138.0	N/A	N/A	N/A	N/A	0.0	0.00%
Number of Published Articles on CPRIT-Funded Research Projects	1,000	N/A	N/A	N/A	N/A	0	0.00%
Number of New Jobs Created and Maintained	3,000	N/A	N/A	N/A	N/A	0	0.00%

Variance Explanations

Number of Entities Relocating to TX for Cancer Research Related Projects
CPRIT prevention grantees have continued to be successful at delivering cancer prevention education and clinical services to more people than they anticipated, stretching their CPRIT-grant funds further to serve Texans. They continue to provide cancer prevention clinical services such as mammograms and colonoscopies.
This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and relocate operations to Texas. A company must meet 4 of CPRIT's 7 criteria for a relocation to be considered complete.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
2018	$300,000,000	September 29, 2017	$ 68,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		March 8, 2018	$ 99,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		July 11, 2018	$ 55,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 222,200,000				
2019		September 21, 2018	$ 222,200,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded $222.2M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.720632%
2019	$300,000,000	September 21, 2018	$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.720544%
2019		March 28, 2019	$ 77,725,000		Commercial Paper Notes	Series A, Taxable		
2019		July 12, 2019	$ 54,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 207,700,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2020		September 16, 2019	$ 64,300,000		Commercial Paper Notes	Series A, Taxable		
2020		January 9, 2020	$ 52,000,000		Commercial Paper Notes	Series A, Taxable		
2020		April 23, 2020	$ 237,720,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2020	Par amount of refunding: Refunded $248.025M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	$ 115,000,000		G.O. Bonds	Taxable Series 2020	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	$ 119,750,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2020	Par amount of refunding. Refunded $120.525M of Taxable Series 2011	
				$ 231,300,000				
2021	$300,000,000	September 11, 2020	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
2021		January 14, 2021	$ 59,000,000		Commercial Paper Notes	Series A, Taxable		
2021		April 29, 2021	$ 68,900,000		Commercial Paper Notes	Series A, Taxable		
2021		August 12, 2021	$ 57,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 260,300,000				
2022	$300,000,000	September 28, 2021	$ 87,000,000		Commercial Paper Notes	Series A, Taxable		
2022		November 18, 2021	$ 334,745,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2021B	Par amount of refunding: Refunded $347.300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		November 18, 2021	$ 139,565,000		G.O. Bonds	Taxable Series 2021B	New money proceeds of $144.800M	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		November 18, 2021	$ 108,005,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2021B	Par amount of refunding: Refunded $108.660M of Taxable Series 2014B	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		July 14, 2022	$ 66,300,000		Commercial Paper Notes	Series A, Taxable		
				$ 298,100,000				
2023	$300,000,000	September 20, 2022	$ 79,500,000		Commercial Paper Notes	Series A, Taxable		
2023		March 2, 2023	$ 66,000,000		Commercial Paper Notes	Series A, Taxable		
2023		April 6, 2023	$ 79,000,000		Commercial Paper Notes	Series A, Taxable		
2023		June 15, 2023	$ 59,200,000		Commercial Paper Notes	Series A, Taxable		
2023		August 29, 2023	$ 350,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2023	Par amount of refunding	Fixed Rate Bonds All-In-True Interest Cost 5.020317%
2023		August 29, 2023	$ 14,600,000		G.O. Bonds	Taxable Series 2023	Par amount of new money proceeds	Fixed Rate Bonds All-In-True Interest Cost 5.020317%
				$ 298,300,000				
2024	$ 300,000,000	October 4, 2023	$ 92,800,000		Commercial Paper Notes	Series A, Taxable		
		November 15, 2023	$ 92,800,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2023A	Par amount of refunding	Fixed Rate Bonds All-In-True Interest Cost 6.129887%
		November 15, 2023	$ 205,600,000		G.O. Bonds	Taxable Series 2023A	Par amount of new money proceeds	Fixed Rate Bonds All-In-True Interest Cost 6.129887%
				$ 298,400,000				
2025	$ 300,000,000	September 24, 2024	$ 86,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 4.87%
		December 30, 2024	$ 69,500,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 4.65%

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
				$ 155,500,000				
TOTAL ISSUED TO DATE				**$ 3,265,600,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL, DEPUTY EXECUTIVE AND CHIEF OPERATING OFFICER

SUBJECT: CPRIT INNOVATIONS VII CONFERENCE UPDATE

DATE: FEBRUARY 11, 2025

CPRIT staff have begun meeting with the Innovations Event Management (IEM) team to develop the request for proposal (RFP) for a conference venue. In developing the solicitation, the dates of national cancer conferences occurring in 2026 are being taken into consideration as blackout dates for the CPRIT conference. Once finalized CPRIT will distribute the solicitation to venues statewide.

CPRIT program staff are beginning to develop topics for conference plenaries and breakout sessions.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MARK DALLAS LOEFFLER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	FEBRUARY 11, 2024

These are highlights of the CPRIT communications team efforts since the November Oversight Committee meeting.

Publications / Websites

- Published the *2024 Texas Cancer Plan* online in December; promoted via press release, listserv, and social media
- Finished content and design, published *2024 CPRIT Annual Report* in accordance with legislative deadline January 31; promoted with web article, listserv emails and social media

Audio / Video

- Created a new "Clinical Trials Primer" video based on interview by Dr. David Gerber, UTSW for Annual Report

Media Relations

The communications team posted and distributed several media advisories and press releases related to CPRIT programs and news:

- Press Release (November 20): State cancer agency awards $89 million in grants to Texas institutions and companies
- Press Release (December 18): 2024 Texas Cancer Plan Now Available
- News Article (January 31): 2024 CPRIT Annual Report Now Available Online

News Interviews

- Earned first sit-down, in-studio TV interview with new CPRIT CEO (KXAN Nov 2024)
- Completed live interview re: CPRIT grants after November OC meeting. (KXAN)

Direct Communication

The communications team distributed the following listserv emails to our list since the August meeting:

- PRESS RELEASE: November 2024 OC Meeting (11/20/24)

- Proposed Changes to Current Agency Rules (12/12/24)
- 2024 Texas Cancer Plan Announcement (12/18/24)
- CPRIT Updated Policies and Procedures (1/5/25)
- CPRIT Academic Research Program Releases Cycle 26.1 RFAs (1/14/25)
- Upcoming Event: 2025 ACS CAN Houston Research and Health Equity Breakfast (1/21/25)
- 2024 Annual Report Launch – Legislators and State Leaders (1/31/25)
- 2024 Annual Report Launch – General Public (2/3/25)
- Upcoming Event: 2025 SITC Cancer Immunotherapy Winter School (2/5/25)
- Upcoming Event: UTRGV 3rd International Conference on Cancer Health Disparities and the School of Medicine Research Symposium 2025 (2/7/25)

Newsclips
We shared **541** articles and social media posts through CPRIT ENews from November 11, 2024, to February 6, 2025.

Social Media Statistics
Social Media from November 9, 2024, to February 6, 2025.

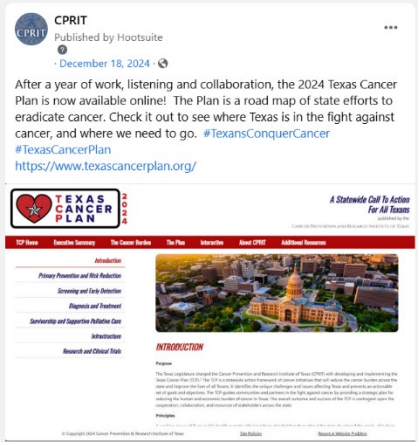
Facebook	X	LinkedIn
5,327 total views	**3.67%** engagement rate	**7.93%** engagement rate
1,340 Fans (+33)	**3,565** followers (-68)	**4,432** followers (+280)
Top Post Views: **576** (11/20/24)	Top Tweet: **12,654** impressions (1/15/25)	Top Post: **13,623** impressions (1/31/25)

Website Hits and Visitors November 9, 2024, to February 6, 2025.

Users	New Users	Sessions (Visits)	Pageviews	Engage Rate
21,259	**19,698**	**34,516**	**62,742**	**45.28%**

Top Performing Posts

FACEBOOK: 12/18/24



After a year of work, listening and collaboration, the 2024 Texas Cancer Plan is now available online! The Plan is a road map of state efforts to eradicate cancer. Check it out to see where Texas is in the fight against cancer, and where we need to go. #TexansConquerCancer #TexasCancerPlan https://www.texascancerplan.org/

X: 1/15/25

CPRIT releases six new request for applications for cancer research grants. View complete RFAs with deadlines, requirements, and instructions at the link below. #TexansConquerCancer http://ow.ly/clhJ50Ogeyo

LINKEDIN: 1/31/25

We mourn the loss and celebrate the life of Ann Tanabe, CEO of BioHouston.

In Memoriam

Ann Tanabe

A vibrant leader and tireless advocate for bioscience. A resounding voice for the Texas life science industry and the promise it holds for all mankind.

And a true friend to CPRIT who shared our common commitment to conquer cancer.

Ann, you will be missed.