CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CPRIT Product Development Research

FY 2022 Cycle 2 (22.2) TXCO, RELCO, SEED RFAs

Webinar: November 16, 2021

Webinar Presenters

CPRIT Product Development Research:

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CPRIT Reviewers:

David Shoemaker, PhD
Deputy Chair, Product Development Review Council

Jim Jordan, MBA
Reviewer, Product Development

Agenda and Q&A

Agenda

- Overview – CPRIT Product Development Research Program and available RFA grant mechanisms (SEED, TXCO, RELCO)
- Q&A Session

Q&A

- Attendees will have their video/mic disabled during the webinar.
- Attendees may submit questions at any time via Zoom Q&A.
- Questions will be addressed at the end of the presentation.

CPRIT Award Data

1,679 Awards Totaling $2.86 Billion

Academic Research
1,371 awards, $2.06 Billion

Product Development
50 awards, $493.2 Million

Prevention
258 awards, $300.3 Million

- 43 companies funded, including 14 relocation companies
- 28 TXCO, 14 RELCO, 8 SEED awards
- 6 companies with multiple awards
- 19 awardee companies conducting active clinical trials

- $5.09 billion direct follow-on funding raised by companies (> 10 to 1)
- 1100+ jobs created in Texas
- Products launched

Belzutifan for cancers associated with von Hippel-Lindau disease (Peloton acquired by Merck)

Visualase MRI-Guided Laser Ablation (acquired by Medtronic)

Multiple NGS products developed/launched by Asuragen (acquired by Bio-Techne)

OncologyMAP developed by RBM (acquired by Myriad, purchased by Q2 Solutions)

Product Development Research Priorities

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available; 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 institutions**
- Supporting **new company formation in Texas or attracting promising companies to Texas** that will recruit staff with life science expertise, especially experienced C-level staff, to lead to seed clusters of life science expertise at various Texas locations
- Providing appropriate **return on Texas taxpayer investment**

Product Development Research RFAs

- **Objectives**
  - Identifying and funding projects to develop **novel drugs, diagnostic applications, medical devices and other non-traditional products** with focused relevance to **cancer** treatment and prevention
  - Funding **Texas-based companies and companies willing to relocate to Texas** that are most likely to bring important products to the marketplace
  - Providing funding that promotes the **translation of research at Texas institutions into startup companies** able to compete in the marketplace

Product Development Research Award Mechanisms

- **Texas Company Awards (TXCO)**
  - Early-stage companies already located in Texas
  - Up to $20 million; 3 years
- **Company Relocation Awards (RELCO)**
  - Early-stage companies willing to relocate to Texas
  - Up to $20 million; 3 years
- **Seed Awards (SEED)**
  - Startup companies; already based in Texas or willing to relocate to Texas
  - Up to $3 million; 3 years

Product Development Research Investments

Lubbock

CerRx

San Antonio

PELICAN Therapeutics

NanoTx THERAPEUTICS

EMTORA BIOSCIENCES

College Station

FUJIFILM Diosynth biotechnologies

CALIBER biotherapeutics

DFW Metroplex

BARRICADE THERAPEUTICS

DIALECTIC THERAPEUTICS

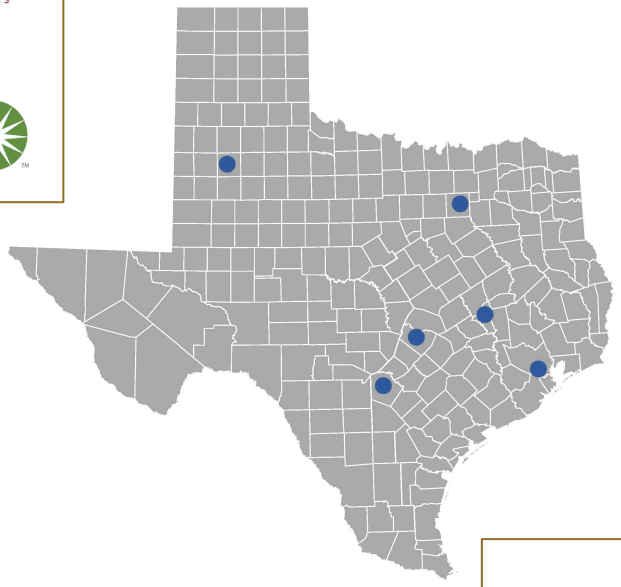
NEXEON

ONCOMANO

Peloton Therapeutics

TMIT Revolutionize Image-guided Radiotherapy

PERIMETER



Houston

aravive BIOLOGICS Outcompeting Cancer

allo Vir

ALLterum Therapeutics

ASYLIA THERAPEUTICS

Bellicum

Cell Medica

DNAtrix THERAPEUTICS

ESSA

Hummingbird BIOSCIENCE

immatics

IMMUNOGENESIS

InGeneron

INSTAPATH

Iterion

invectys CANCER IMMUNOTHERAPEUTICS

ANOVAC A Division of ANSUN BIOPHARMA

Magnolia Tejas Corporation

MARKER Therapeutics

MEDICENNA THERAPEUTICS CORP.

PULMOTECT

Salarius PHARMACEUTICALS The Cancer Epigenetics Company

VISUALASE

Austin

aeglea BIOTHERAPEUTICS

apollo endosurgery

Asuragen®

Curtana PHARMACEUTICALS

FORBIUS

tem MOLECULAR TEMPLATES

MYRIAD RBM

miRNA THERAPEUTICS

State of Texas University Spin-Outs

Lubbock

CerRx

San Antonio

PELICAN Therapeutics

NanoTx THERAPEUTICS

EMTORA BIOSCIENCES

DFW Metroplex

BARRICADE THERAPEUTICS

DIALECTIC THERAPEUTICS

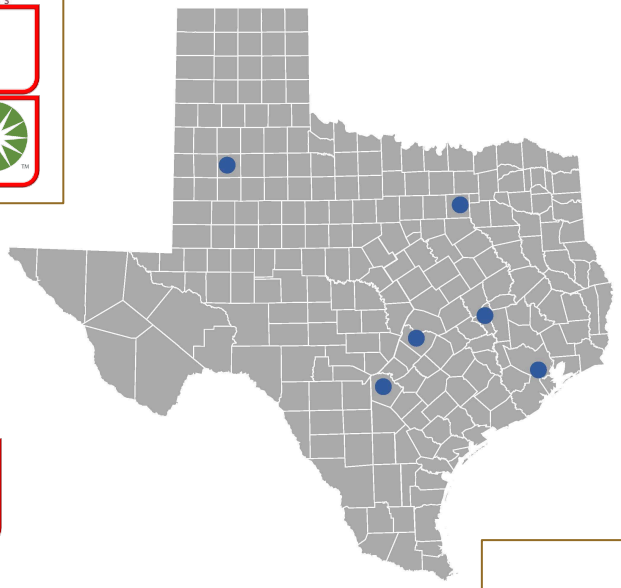
NEXEON

ONCONANO

Peloton Therapeutics

TMIT Revolutionize Image-guided Radiotherapy

PERIMETER



College Station

FUJIFILM Diosynth biotechnologies

CALIBER biotherapeutics

Houston

aravive BIOLOGICS Outcompeting Cancer™

allo Vir

ALLterum Therapeutics

ASYLIA THERAPEUTICS

Bellicum

Cell Medica

DNAtrix THERAPEUTICS

ESSA

Hummingbird BIOSCIENCE

immatics

IMMUNOGENESIS

InGeneron

INSTAPATH

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VISUALASE

Austin

aeglea BIOTHERAPEUTICS

apollo endosurgery

Asuragen®

Curtana PHARMACEUTICALS

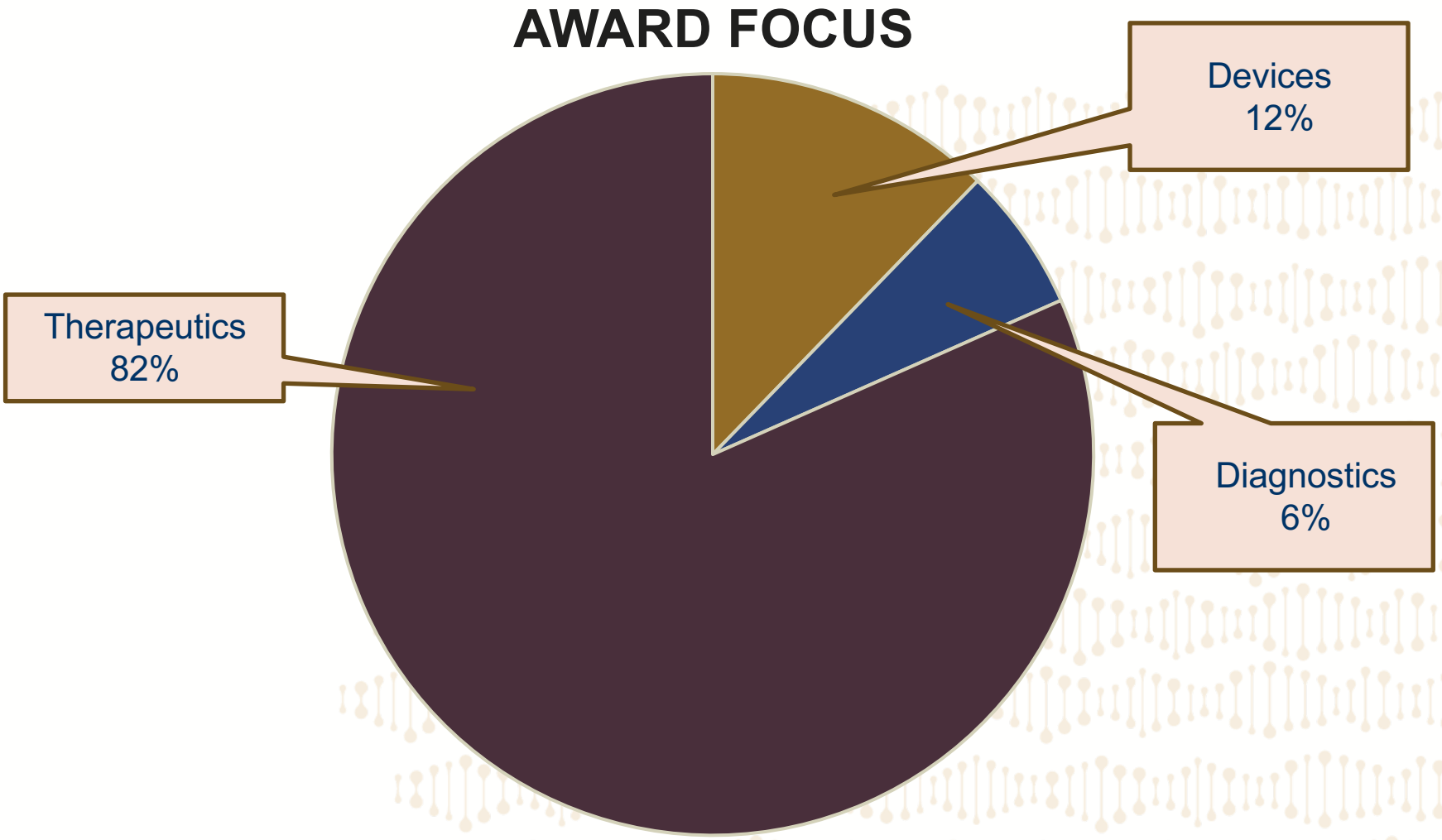
FORBIUS

tem MOLECULAR TEMPLATES

MYRIAD RBM

miRNA THERAPEUTICS

Current Product Development Portfolio Mix



FY2022 Cycle 2: Product Development Research Award Mechanisms

- **Texas Company Awards (TXCO)**
  - Early-stage companies already located in Texas
  - Up to $20 million; 3 years
- **Company Relocation Awards (RELCO)**
  - Early-stage companies willing to relocate to Texas
  - Up to $20 million; 3 years
- **Seed Awards (SEED)**
  - Startup companies; already based in Texas or willing to relocate to Texas
  - Up to $3 million; 3 years

Key Points to Consider, Part 1

- **Contracted relationship with CPRIT**
- **50% match requirement for Awards up to $20 million**
  - For example, a company that applies for $1 million in CPRIT funding must raise $500,000 in external matching funds
  - For recipient of more than one CPRIT award – details on next slide
- **CEO Requirement**
  - Must have a chief executive officer (CEO) as part of the applicant's management team prior to submitting an application
- **Annual Progress Report Review** – must meet goals/objectives to continue funding

Key Points to Consider, Part 2

- **50% match requirement for Awards up to $20 million**
  - For example, a company that applies for $1 million in CPRIT funding must raise $500,000 in external matching funds (for every $1 company match, CPRIT funds $2). In this example, the total budget for the project is $1.5 million.

- **Match requirements for Multiple Awards with combined value over $20 million**
- For companies that have received **more than one award**, matching funds requirements are linked to the **combined total dollar amount** of awards committed to the company.
  - Up to $20 million dollars (in total): 1:2 match requirement
  - Greater than $20 million dollars (in total): 1:1 match requirement
  - Greater than $30 million dollars (in total): 2:1 match requirement

Multiple award examples:

SEED awardee at $3 million (first award, 1:2) and $15 million (second award, 1:2):
Combined $18 million

TXCO awardee at $6 million (first award, 1:2) and $20 million (second award, 1:1):
Combined $26 million

TXCO awardee at $6 million (first award, 1:2) and $12 million (second award, 1:2):
Combined $18 million

Key Points to Consider, Part 3

- **Texas Location Criteria**
  - Awardees must; either be based in Texas or commit to become Texas-based
  - an awardee is considered to be Texas-based if it fulfills a majority of the following criteria:

1. The US headquarters are physically located in Texas.
2. The Chief Executive Officer resides in Texas.
3. A majority of the company's personnel, including at least 2 other C-level employees (or equivalent) reside in Texas.
4. Manufacturing activities take place in Texas.
5. At least 90% of grant award funds are paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors.
6. At least 1 clinical trial site is in Texas.
7. The company collaborates with a medical research organization in Texas, including a public or private institute of higher education.

Points to Consider, Part 4

- **Direct link between Goals and Objectives and funding**
  - Release of funds will be dependent upon the completion of the applicant's proposed Goals & Objectives for each project year.
  - Funding will be tranched by project year budget and completion of the Goals & Objectives submitted in the applicant's proposal.
- **Advance Payments: Key Takeaways**
  - Are tied to successful completion of prior year's milestones
  - May request up to 50% of annual project budget at a time
  - Awardee must demonstrate 90% spend of previous advance before requesting next advance → not a fast process
  - Awardees may need to rely on matching funds for cash flow needs
  - More details: Section 8.2.2 of CPRIT Policies and Procedures Guide

Key Points to Consider, Part 5

- **Revenue sharing commitment**
  - **Therapeutics: 3-5% royalty until 4X the award amount paid to Texas. After 4X award amount is paid to Texas, royalty reduced to 0.5% through patent expiration or loss of market exclusivity, whichever is longer.**
    - For example, therapeutics awardee that receives a $10 million CPRIT award pays 3-5% in royalties (depending on the amount of cumulative revenue) until the total royalty payments equal $40 million, at which point royalties would drop to 0.5% through patent expiration or loss of market exclusivity, whichever is longer.
  - **Devices/Diagnostics/Services: 2.5% royalty until 2.5X the award amount paid to Texas. Then royalty reduced to 0.5% through patent expiration or loss of market exclusivity, whichever is longer.**
    - For example, diagnostics awardee that receives a $10 million CPRIT award pays 2.5% in royalties (depending on the amount of cumulative revenue) until the total royalty payments equal $25 million, at which point royalties would drop to 0.5% through patent expiration or loss of market exclusivity, whichever is longer.
  - **More details:** https://www.cprit.state.tx.us/our-programs/product-development-research/revenue-sharing/

Multi-Stage Peer Review Process

FY 2022 Cycle 2

Application Submission: Companies submit grant proposals by deadline
Opens Dec 1, 2021
Closes Jan 26, 2022

Screening Teleconference: Initial Grant Proposal Review and Scoring

March 2022

Peer Review Meeting: Applicant Presentations (virtual teleconference)

April 2022

Due Diligence Review

April 2022 – July 2022

Program Integration Committee Review

August 2022

Oversight Committee Review and Approval

August 2022

FY 2022 RFA Key Dates

FY 2022 Cycle 2

RFAs Released	November 3, 2021
Application Portal Opens	December 1, 2021
Applications Due	January 26, 2022
In-Person Presentation	April 2022
Award Notification	August 2022

FY 2023 Cycle 1

RFA Release Date	June/July 2022
Applications Due	August 2022
Award Notification	February 2023

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Hallmarks of a Fundable Application
Reviewer Perspectives

David Shoemaker, PhD
Deputy Chair, Product Development Review Council

Jim Jordan, MBA
Peer Reviewer, Product Development

Invest in Commercially Viable Projects

SEED Awards:

- Startups, early-stage commercial concept
- Novel technology, may not be completely at product stage
  - Drugs and Biologics, multiple candidates, no lead
  - Devices, early prototype, not fieldable
  - Diagnostics, may have a research test or Laboratory Developed Test (LDT)
- Strong value proposition with preliminary business plan
- Science-based personnel accessing commercial product development consultants
- Demonstrated understanding of the commercial product development process IND/IDE (clinical, preclinical, CMC, regulatory)

TXCO/RELCO Awards:

- Newly established or established companies
- Novel technology, more likely at product stage
  - Drugs and Biologics, established lead (IND within a year)
  - Devices, commercial-ready prototype (IDE within a year)
  - Diagnostics, commercial-ready prototype (IDE within a year)
- Viable commercial concept with strong Value Proposition and business plan
- Veteran, experienced product development team (fewer consultants)
- Veteran, experienced management team, likely to have secured independent funds
- Deep understanding of the of commercial product development process and marketplace (clinical, preclinical, CMC, regulatory, statistical, marketing, reimbursement, program management, post-market surveillance, competitive landscape, product life cycle, pipeline development, distribution strategy, partnering strategy)

SEED: Early Development Stage Award

- Startup companies
- ~2 - 3 years from filing IND/IDE
- Early Pharmacodynamic Preclinical Proof of Concept
- Plans for how to collect preliminary preclinical safety data
  - Secondary pharmacology studies (specificity)
- Preliminary Development Plans (Clinical, Preclinical, CMC, Regulatory)
- Preliminary Commercialization Strategy
  - Preliminary understanding of competitive landscape and path to market

TXCO/RELCO Award

- Established company, one year from filing IND/IDE or in the Clinic
- Established Proof of Concept
- Completed Preliminary Assay Validation Work
- Completed Pilot Toxicology Studies (most sensitive species identified)
- Completed Initial CMC Studies (initial small-scale batches)
- Management and Disciplinary Expert Personnel (Medical/Clinical, Preclinical, CMC, Regulatory, Commercial) Employed or Identified
- Completed Target Product Profile and/or Integrated (Clinical, Nonclinical, CMC, Regulatory) Product Development Plan through to marketing application
- Completed Intellectual Property Strategy and Initial Filings
- Preliminary Commercialization Plan

What makes a strong device/diagnostic application?

	Medical Device	Diagnostic
Market potential	• ↑ $250 million segment	• ↑ $100 million segment
Sales & marketing (commercialization plan)	• ↑ New category or improvement of existing category • Direct or distribution strategy • Formulary & buying group strategy	• New category or test not offered by major Dx player • Direct or distribution strategy • Kit/product or CLIA
Technology & IP (development plan)	• Existing PCT's or patents • Adequate IP landscape analysis • Design system requirement plan	• Existing PCT's or patents • Trade secrets, proprietary know-how
Clinical evidence (clinical plan)	• Bench data • Biocompatibility analysis • Animal data and maybe FIH	• Human clinical data on sensitivity (w/ disease), & specificity (w/o) • Competitive comparable performance data if existing category, materiality if not
Regulatory & reimbursement	• Pathway: BLA, PMA, 510k • Existing DRG, ICD and/or CPT • Animal data and maybe FIH	• CLIA or PMA/510k pathway • Coding plan for Part A & Part B, new or existing
Team	• Technical team in place • Regulatory consultants engaged	• Technical team in place • Regulatory consultants engaged • CLIA experienced personnel in operations
Revenue	• None	• CLIA should have some revenue

Contacts:

Questions: Application Portal → CPRIT Help Desk

Phone: 866-941-7146

Email: Help@CPRITGrants.org

Monday through Friday, 7 a.m. to 4 p.m. CT

Questions: RFAs → Rosemary French

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CPRIT Website: https://www.cprit.texas.gov/

Q&A

- Submit questions via Zoom Q&A