Cancer Prevention & Research Institute of Texas

CPRIT Product Development Research

FY 2021 Cycle 1 (21.1) TXCO, RELCO, SEED RFAs

Webinar: November 19, 2020

Webinar Participants

Hosts:

Cindy WalkerPeach, PhD
Chief Product Development Officer

Rosemary French, MBA
Senior Program Manager

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 Program and available RFA grant mechanisms (SEED, TXCO, RELCO)
- Live Q&A Session

Q&A

- Participant lines will be muted during the webinar.
- Participants may submit questions at any time.
- Questions will be addressed at the end of the presentation.
- Please submit your questions using “Questions Box” on the GoToWebinar control panel and clicking SEND.

CPRIT Grant Award Data

1,576 Awards Totaling $2.64 Billion

Academic Research
1,283 awards, $1.88 Billion

Product Development
49 awards, $479.9 Million

Prevention
244 awards, $277.7 Million

- 42 companies funded, including 14 relocation companies
- 27 TXCO, 14 RELCO, 8 SEED awards
- 6 companies with multiple awards
- 17 awardee companies conducting active clinical trials

- $3.37 billion direct follow-on funding raised by companies (> 7 to 1)
- 700+ jobs created in Texas
- Products launched
  Visualase MRI-Guided Laser Ablation (acquired by Medtronic)
  Multiple NGS products developed/launched by Asuragen
  OncologyMAP developed by RBM (acquired by Myriad)

2021 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
- Stimulation 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 Awards

- **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

DFW Metroplex

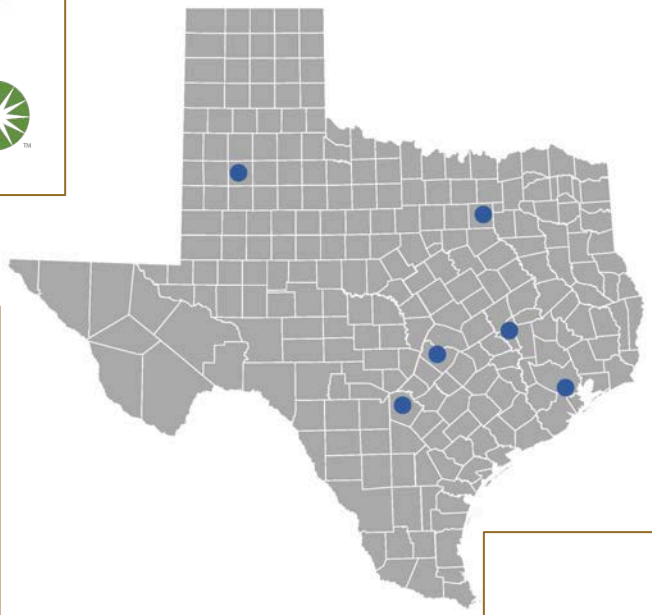
BARRICADE THERAPEUTICS
DIALECTIC THERAPEUTICS
NEXEON
ONCONANO
Peloton Therapeutics
TMIT
PERIMETER

Houston

aravive BIOLOGICS
allo Vir
ALLterum Therapeutics
ASYLIA THERAPEUTICS
Bellicum
Cell Medica
DNAtrix THERAPEUTICS
ESSA
Hummingbird BIOSCIENCE
immatics
IMMUNOGENESIS
InGeneron
INSTAPATH
Iterion
invectys
kealex THERAPEUTICS
Magnolia Tejas Corporation
MEDICENNA THERAPEUTICS CORP.
PULMOTECT
Salarius PHARMACEUTICALS The Cancer Epigenetics Company
VISUALASE

San Antonio

PELICAN Therapeutics
NanoTx THERAPEUTICS
EMTORA BIOSCIENCES



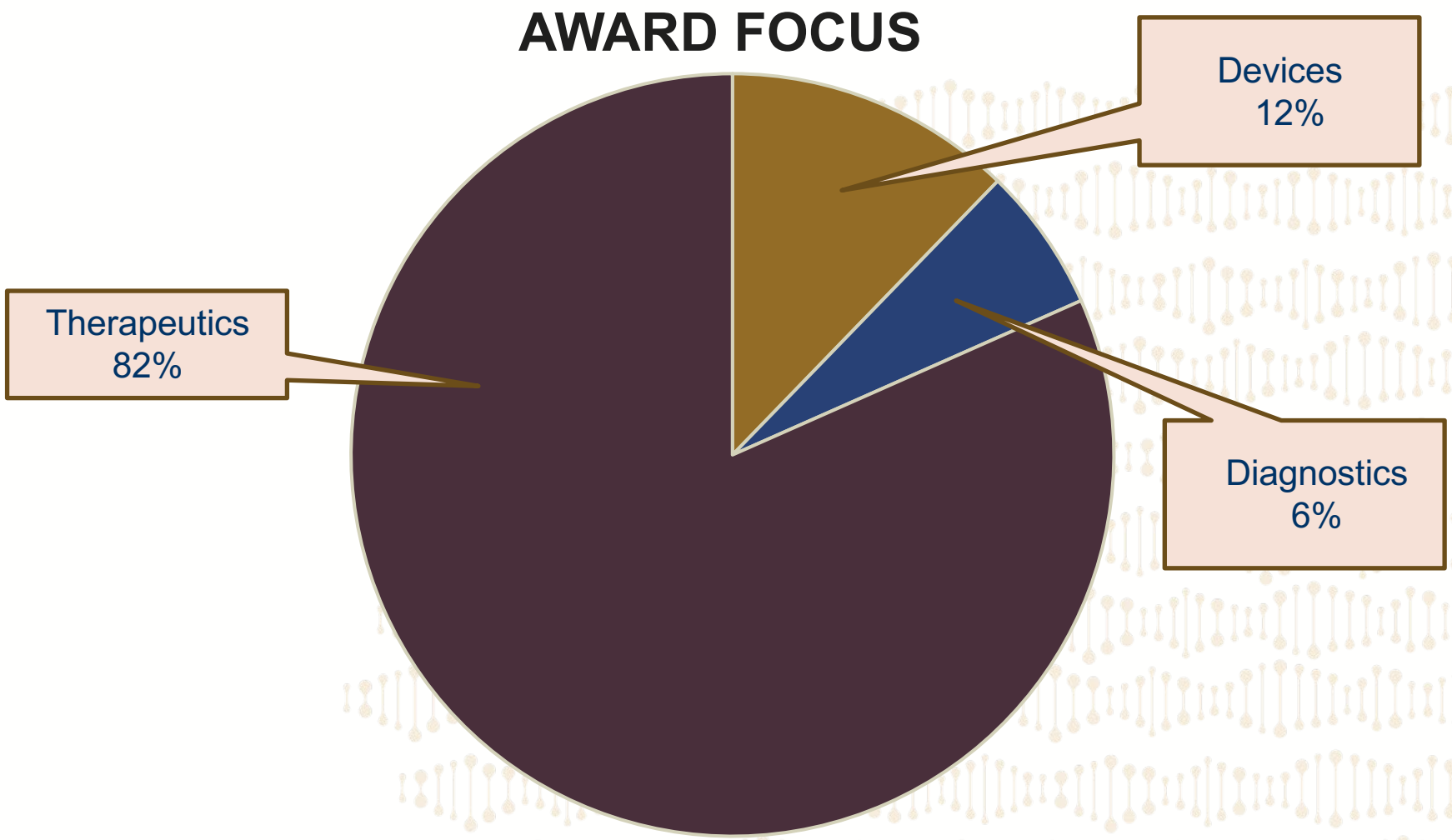
College Station

FUJIFILM Diosynth biotechnologies
CALIBER biotherapeutics

Austin

aeglea BIOTHERAPEUTICS
apollo endosurgery
Asuragen
Curtana PHARMACEUTICALS
FORBIUS
tem MOLECULAR TEMPLATES
MYRIAD RBM
miRna THERAPEUTICS

Product Development Research Portfolio Mix



FY2021 Cycle 1:
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

Annual Progress Report Review – must meet goals/objectives to continue funding

50% match requirement

- For example, a company that applies for $1 million in CPRIT funding must raise $500,000 in external matching funds

CEO Requirement

- Must have a chief executive officer (CEO) as part of the applicant's management team prior to submitting an application

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 2

- **Methods of Funds Disbursement**
  - CPRIT utilizes 2 methods of disbursement of grant funds: (1) reimbursement and (2) advancement. Under the reimbursement method, the grantee is expected to finance its operations with its own working capital. Under the advancement method, CPRIT disburses grant funds in advance of the grantee incurring expenses.
- **Direct link between Goals and Objectives completion and funding**
  - Funding will be tranched and tied to the achievement of contract-specified milestones. The contract-specific milestones are the Goals & Objectives submitted by the applicant within the proposal.
  - The progress-based release of funds will be dependent upon the completion of the applicant's proposed Goals & Objectives for each project year.
- **Advance Funds Method**
  - CPRIT will advance up to 50% of the project year budget at one time.
  - The grantee must be in good fiscal and programmatic standing and have expended 90% of the advanced funds before requesting the next advance.
  - Approval of advance payment of grant funds is not guaranteed. In most cases, the disbursement of grant funds may occur only after CPRIT approves required reports, such as the matching certification/verification form and the tranche report.
  - More info in Section 8.2.2 of CPRIT Policies and Procedures Guide

Key Points to Consider, Part 3

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%.**
  - 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%

- **Devices/Diagnostics/Services: 3-5% royalty until 2.5X the award amount paid to Texas. Then royalty reduced to 0.5%.**
  - For example, diagnostics 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 $25 million, at which point royalties would drop to 0.5%

- **More details:** https://www.cprit.state.tx.us/our-programs/product-development-research/revenue-sharing/

Multi-Stage Peer Review Process

FY 2021 Cycle 1

Application Submission: Companies submit grant proposals by deadline January 27, 2021

Screening Teleconference: Initial Grant Proposal Review and Scoring

March 2021

Peer Review Meeting: Applicant Presentations (virtual teleconference)

April 2021

Due Diligence Review

May-July 2021

Program Integration Committee Review

August 2021

Oversight Committee Review and Approval

August 2021

Product Development Research: FY 2021 RFA Key Dates

FY 2021 Cycle 1

RFAs Released	November 9, 2020
Application Portal Opens	December 2, 2020
Applications Due	January 27, 2021
In-Person Presentation	April 2021
Award Notification	August 2021

FY 2022 Cycle 1 (tentative)

RFA Release Date	Summer 2021
Applications Due	Summer 2021
Award Notification	February 2022

Cancer Prevention & Research Institute of Texas

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 Grant

- Startup companies
- ~2 - 3 years from filing IND/IDE
- Early Pharmacodynamic Proof of Concept
  - Supported by rigorous pharmacology data in multiple models
- 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 Development Stage Grant

- 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

Contact Info

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: Application Content and RFAs:

Rosemary French, Senior Program Manager, Product Development

Phone: 512-305-7676

Email: rfrench@cprit.texas.gov

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

Q&A

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