



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Workshop

May 19, 2016

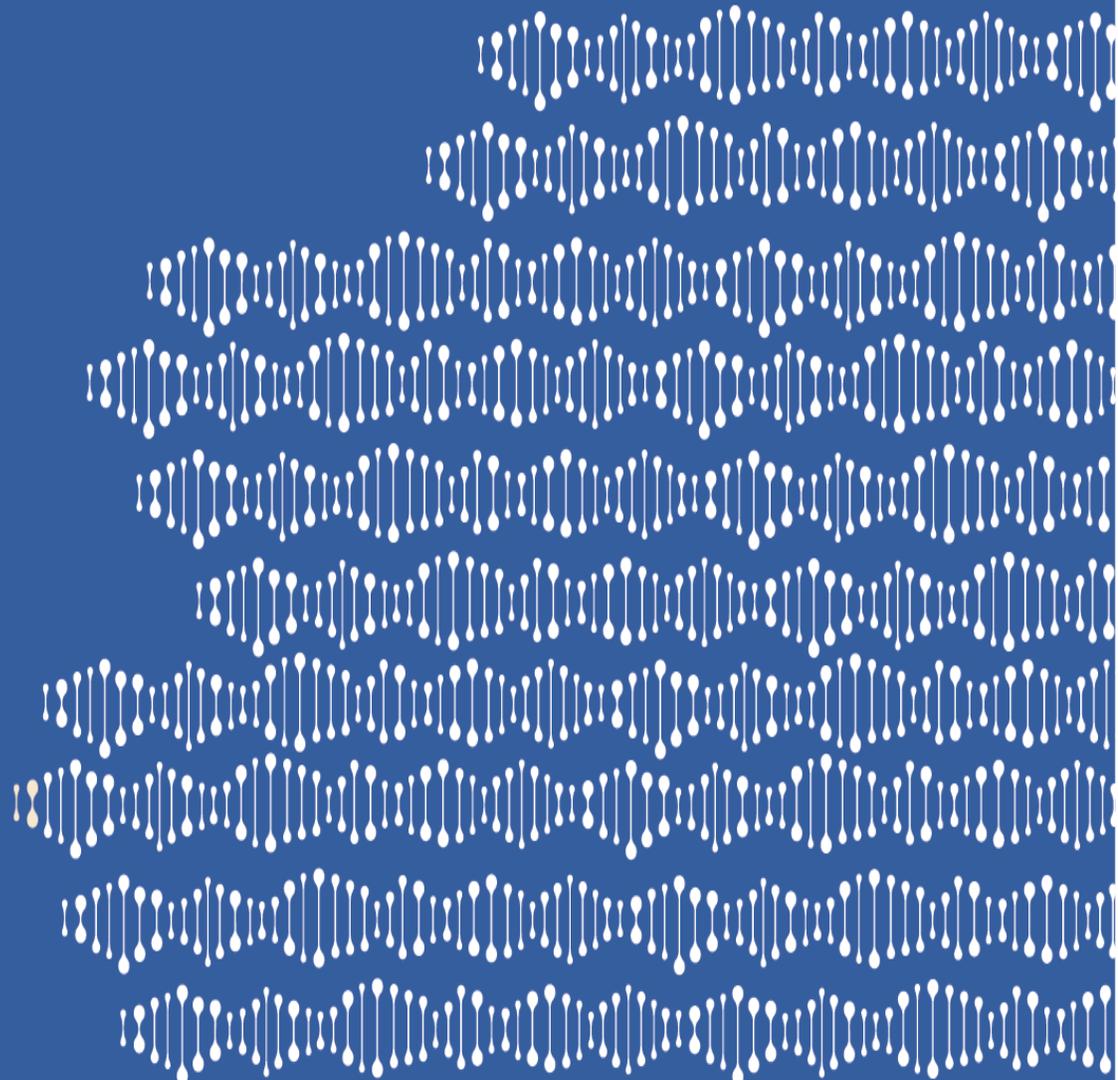


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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

Robert E. Johnson Conference Center
1501 N. Congress Ave, Austin, Texas 78701
Central Room

May 19, 2016
8:30 a.m.

The Oversight Committee may discuss or take action regarding 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 purposes permitted by the Act.

1. Call to Order
2. Roll Call/Excused Absences
3. Work Session Overview
4. Strategic Planning
5. Program Priorities and Program Budgeting
6. Adjourn



CANCER PREVENTION & RESEARCH
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MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: MAY 19, 2016, WORK SESSION OVERVIEW
DATE: MAY 12, 2016

Summary:

This memorandum provides an overview of what to expect at the Oversight Committee Work Session on May 19, 2016. Additional work session materials are provided in the separate memorandum “CPRIT Work Session Preparation”.

Discussion:

The work session is designed to begin Oversight Committee (OC) and staff discussion concerning future directions of CPRIT.

The meeting will involve informal open discussion facilitated by OC members and pertinent staff seated at a table arrangement (see Attachment). Although informal, the discussion will be structured into two highly interrelated parts, summarized as follows.

Strategic Plan

Over the past two months CPRIT staff and Dr. Bill Rice, representing the OC, have met for over twenty hours on several occasions to develop a *draft* agency strategic plan distinct from that required by state law used in setting state appropriations. Jeff Hahn of Hahn Public Communications has served as facilitator of these discussions. Dr. Rice will present the current *draft* with Vision, Mission, Core Values, Strategic Objectives, Key Tactics and Action Plan components. This draft plan outlines the path of the agency, programmatically and operationally, as we start the next five years and prepare for the statutory Sunset process.

Oversight Committee Program Priorities and Program Budgeting

This involves initiating the statutorily required 2017 Program Priorities process for anticipated approval at the November 16, 2016, OC meeting. The Program Priorities are part of what is to be implemented in the strategic plan. In addition, budget planning and decision-making for the two research programs and prevention are driven by the OC Program Priorities.

An overview of the Texas research and development landscape for the life sciences and cancer in particular will be provided along with an analysis of CPRIT's current product development research portfolio. Historical funding by mechanism for Academic Research, Prevention and Product Development Research will also be available to inform the discussion.

Attachment: Seating chart for REJ Conference Room

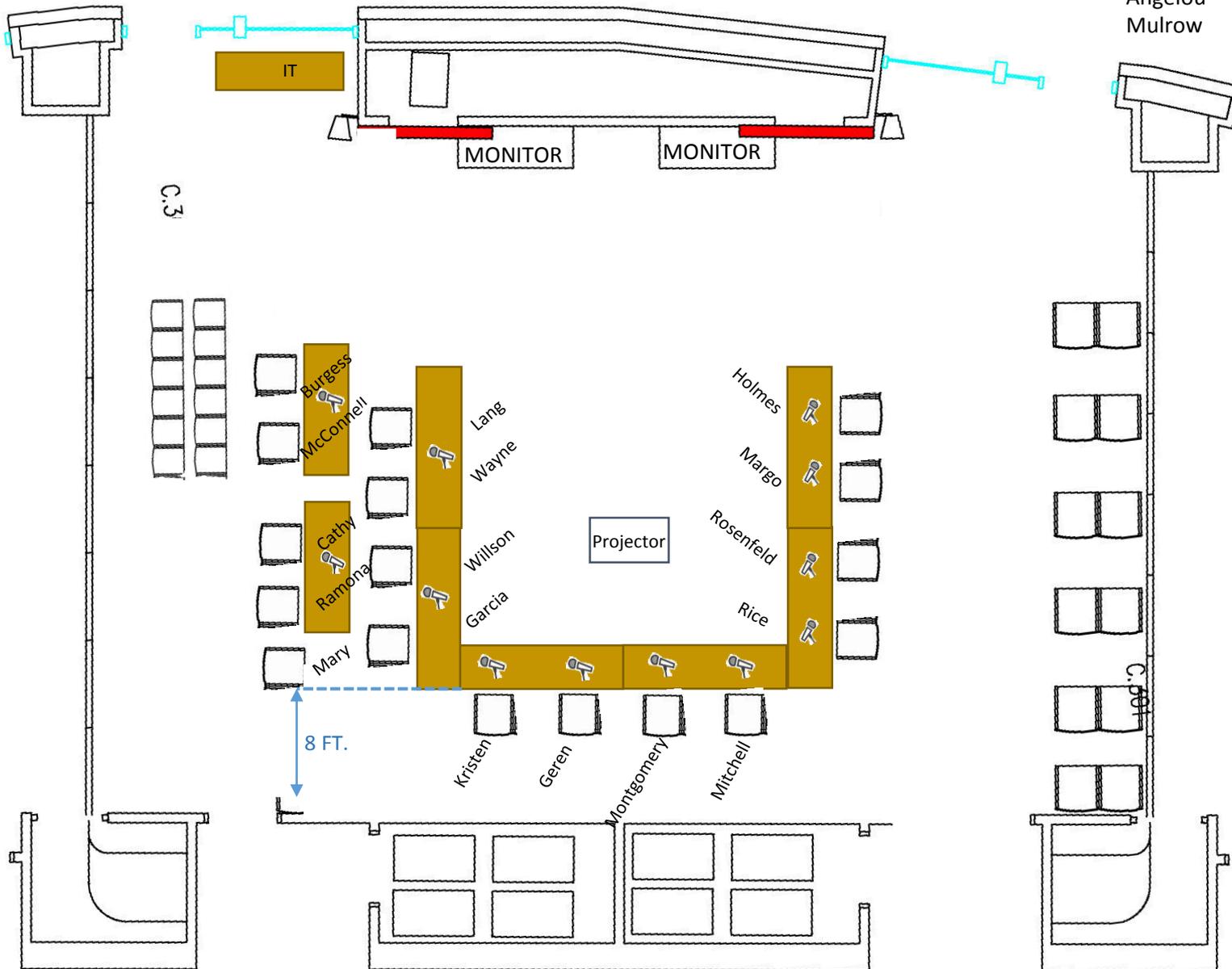
REJ Conference Room

Thursday, May 19, 2016

Not attending:

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Mulrow





CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: STRATEGIC PLANNING DOCUMENT
DATE: MAY 12, 2016

The following document was designed to be an 11 x 17 inch document. For printing and meeting book material purposes it is formatted on 8½ x 11 inch paper. You will be provided an 11 x 17 inch document at the work session.

Vision: Texans conquer cancer.
Mission: CPRIT expedites discoveries and innovations across Texas to reduce the burdens of cancer.
Values: CPRIT acts with the highest standards of ethics, accountability, transparency and excellence.

Strategic Plan Alignment			Performance Dashboard	
Goals	Strategic Objectives	Key Tactics	Action Plans	Performance Measures
Expedite Innovation	1. Support innovative cancer research.	1.1 Fund the very best cancer research.	➤ Emphasize innovation and impact in RFAs and review.	
		1.2 Recruit new cancer researchers to Texas.	➤ Evaluate program outcomes and revise recruitment RFAs as needed.	
		1.3 Enhance the translation of cancer research into clinical practice.	➤ Identify and fill gaps in the product development continuum.	
	2. Support innovative prevention interventions.	2.1 Fund the very best prevention programs.	➤ Emphasize innovation, impact, geographic and population diversity in RFAs and review.	
		2.2 Create and support opportunities for networks to deliver services to the broadest geographic area.	➤ Identify and fill gaps in prevention service and infrastructure needs and create or revise RFAs.	
	3. Focus on unique needs of Texans.	3.1 Understand cancer burden by geography, type and demographics.	➤ Acquire data from DSHS and national reports, include in relevant CPRIT reports. ➤ Use data in identifying prevention and research needs for RFAs.	
	4. Foster statewide collaboration in cancer prevention and research.	4.1 Identify and promote collaborative mechanisms (RFAs).	➤ Work with stakeholders to identify needs, networks, collaboration opportunities.	
			➤ Create and stimulate opportunities for statewide initiatives.	
			➤ Consider deploying more MIRA-like collaboration and coalition RFAs.	
		4.2 Create convening opportunities.	➤ Produce biennial statewide cancer conference.	
			➤ Convene and consult with advisory committees.	
			4.3 Promote collaboration between institutions.	➤ Encourage data sharing. ➤ Encourage core facilities, tissue bank sharing. ➤ Promote shared access to patients and patient data. ➤ Build clinical trial network expertise.
	5. Grow the cancer life science ecosystem in Texas.	5.1 Recruit people with diverse competencies to support the growth of the life sciences industry.	➤ Recruit and develop C-level entrepreneurs to support development of technologies.	
			➤ Stimulate company spin outs. ➤ Recruit companies to Texas.	
		5.2 Facilitate building of unique statewide assets and capabilities.	➤ Support training of healthcare providers and researchers.	
			➤ Support shared core facilities. ➤ Create new jobs.	
	5.3 Strengthen the state's capacity to deliver cancer prevention services.	5.4 Enhance investment in Texas biosciences.	➤ Emphasize improvement in healthcare delivery systems in RFAs. ➤ Promote and educate CPRIT sponsored projects to outside investors.	
	6. Plan for the future.	6.1 Establish priorities across and within Research, Product Development, and Prevention programs.	➤ Identify a promising integrated focus area to accelerate advances in prevention, early detection and treatment for a specific cancer challenge.	
			➤ Design cross-program RFAs to incentivize partnerships and cooperation.	
			➤ Identify and reduce barriers to quickly facilitate funding across programs.	
		6.2 Assess needs, concerns and opportunities seen by the cancer community.	➤ Engage with Texas' executive and legislative membership and public.	
	➤ Meet with cancer organizations. ➤ Use UAC and ACCC to receive cancer community input.			
	6.3 Prepare for Sunset review.		➤ Engage sunset staff for direction. ➤ Identify steps necessary to end award making processes. ➤ Prepare to transition fiduciary control, grant management and investment management to an entity TBD.	

Vision: Texans conquer cancer.
Mission: CPRIT expedites discoveries and innovations across Texas to reduce the burdens of cancer.
Values: CPRIT acts with the highest standards of ethics, accountability, transparency and excellence.

Strategic Plan Alignment			Performance Dashboard	
Goals	Strategic Objectives	Key Tactics	Action Plans	Performance Measures
Engage Stakeholders	7. Assure grant applicants and grantees are served effectively.	7.1 Assure grant processes (application, review, approval, monitoring) are working as intended.	<ul style="list-style-type: none"> ➤ Review process performance metrics including post-approval monitoring to ensure efficiency. 	
	8. Optimize employee engagement.	8.1 Develop and refine an employee recruitment and retention plan.	<ul style="list-style-type: none"> ➤ Review and revise as needed HR policies, staff training & onboarding and engagement activities. ➤ Define non-monetary employee retention tactics. 	
	9. Dialogue with legislators, advocates, grantees, and the public.	9.1 Evaluate program impact and outcomes and communicate through available channels.	<ul style="list-style-type: none"> ➤ Create plan and timeline to communicate achievements and impact to different stakeholders (e.g. 2017, 2019 legislative sessions). ➤ Create new opportunities to communicate messages (e.g. Launch web-based digital news room, significance project). ➤ Document the tangible benefits to Texans of CPRIT investments. 	
Demonstrate Ethics & Accountability	10. Assure all grant processes adhere to all rules and regulations.	10.1 Assure grant management system supports effective grants monitoring.	<ul style="list-style-type: none"> ➤ Define key metrics for adherence to grant applications rules/regulations; review, approval, contracting and post-approval monitoring. 	
		10.2 Continue strong compliance program.	<ul style="list-style-type: none"> ➤ Assure all application steps, reviews and reports are followed. 	
	11. Assure all state administrative and ethics guidelines are followed.	11.1 Report on important aspects of the agency to demonstrate accountability and transparency.	<ul style="list-style-type: none"> ➤ Define key metrics and create reports for key non-grant administrative processes. 	



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
JAMES WILLSON, M.D., CHIEF SCIENTIFIC OFFICER
BECKY GARCIA, PH.D., CHIEF PREVENTION OFFICER
MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER

SUBJECT: CPRIT WORK SESSION PREPARATION

DATE: MAY 12, 2016

This Oversight Committee Work Session begins the discussion of the 2017 Program Priorities, which are scheduled for Oversight Committee adoption in November. While the discussion should address this near-term goal, the groundwork laid in the work session is likely to guide much of the work done by CPRIT for the next five years. We propose that this work session begin by reviewing the Texas research and development (R&D) landscape, current program funding, and the Program Priorities and using these topics to launch a substantive discussion.

The Texas Research and Development Landscape

Earlier this year, Michael Lang, CPRIT's Chief Product Development Officer completed an analysis of the Texas cancer R&D landscape. (See Attachment 1, *Texas Cancer R&D Landscape: Optimizing CPRIT's Impact*). According to his research, the state is underrepresented in federal cancer research award funding and venture capital available for life sciences:

- Despite having 8.4% of the nation's population and 9.4% of the national Gross Domestic Product, Texas receives 7% of National Cancer Institute (NCI) cancer research award funding.
- The state receives 4.4% of National Institutes of Health award funding (a measure of life sciences funding).
- Venture capital invested in Texas life science companies represents just 2.3% of the \$9.4 billion venture capital available nationwide for life sciences.

Considered in light of these metrics, CPRIT's funding has been transformative on a state level. On average, NCI provides \$204 million in cancer research grants to Texas institutions. CPRIT awards roughly the same amount each year, thereby doubling the amount of supported cancer research in Texas.

One measure of this influence is the number of NCI designated Comprehensive Cancer Centers. When CPRIT started operations in 2009, there was only one institution in the state designated as

a Comprehensive Cancer Center. There are now three Comprehensive Cancer Centers, plus one NCI-designated Cancer Center. The designations recognize these institutions' role in the network that serves as the backbone of the national cancer research effort.

CPRIT is also having an impact in product development funding in this state, providing on average \$51 million per year, which increases by nearly 25% the \$216 million in annual venture capital funding invested in life sciences companies in Texas. To date, CPRIT invests 85% of product development funds in companies developing cancer drugs.

Program Funding

State law sets a maximum funding allocation for prevention grants at 10% but is silent on the allocation of funds between Academic Research and Product Development Research. However, the distribution of funds and awards between the two research programs has occurred solely on merit as determined by CPRIT's distinguished peer reviewers. The grant award portfolio is split among its three programs:

- 71.6% of total grant funds awarded to Academic Research
- 18.0% to Product Development Research
- 10.4% to Prevention

The split between Academic Research and Product Development Research is the result of several factors. The Oversight Committee started approving Academic Research awards in late 2009, while the first Product Development Research awards were not made until June 2010. Academic Research releases more Requests for Applications (RFAs) annually and receives a greater number of applications. The Product Development Research review process is longer due to in-person presentations and third party due diligence evaluations that are not part of the Academic Research review process. In fact, recruitment awards, which comprise a significant portion of the Academic Research portfolio, are continuously accepted and are reviewed by the Review Council on a monthly basis.

Funding has been sufficient thus far to award all projects recommended by the review councils of both programs. CPRIT has no indication that the demand for grants or the quality of the applicants will decrease, which means that the CPRIT may soon have more meritorious grant proposals than grant funds available.

Although not based in a formal schema, the discussion of funding priorities has centered on dollars or percentages illustrated by the current program-centric 72-18-10 split. As CPRIT continues to emphasize cross-program opportunities, it may be more instructive to consider CPRIT's grant portfolio based upon the stage of the research project. Typically, it takes 23 years from the time that the research discovery is made in the lab until the patent ends on the resulting drug. (See Attachment 1, pg. 14) During this time, the lab discovery goes through numerous research stages, including proof of concept and preclinical testing (transitional research) and first in human and later stage dosing studies (clinical research).

Viewed from the perspective of research development phases, CPRIT's \$1.341 billion award research portfolio is split in the following manner:

- 15.5% of the funding (\$208.2 million) supports discovery stage research projects
- 25.6% of the funding (\$342.6 million) supports translational research projects
- 30.7% of the funding (\$411.6 million) supports clinical research projects
- 24.9% of funding (\$334.2 million) supports recruitment awards
- 3.3% of funding (\$44.4 million) supports training programs.

Program Priorities

Although no established funding allocations dictate award choices between Academic Research and Product Development Research, the legislature requires the Oversight Committee to establish annual program priorities. The Oversight Committee adopted the current Program Priorities in 2014 and approved them again in 2015. The Oversight Committee's Program Priorities include both program-specific and across-program priorities. (See Attachment 3, *CPRIT Program Priorities for 2016*)

To date, the program-specific priorities are used to guide the development and issuance of RFAs, and inform the Program Integration Committee on balancing the portfolio across the three programs. Although CPRIT funds a broad range of programs and cancer types, the ability to focus on the across-program opportunities distinguishes it from other funding sources. CPRIT's structure presents a unique opportunity for funding projects that span the continuum from discovery to delivery to the public and creating synergy across the spectrum. Currently the across-program priorities are: 1) prevention and early detection initiatives, 2) early translational research, and 3) enhancing Texas' research capacity and life science infrastructure.

Developing the Program Priorities for 2017 provides a fertile field to consider during the work session:

- Without doubt, CPRIT's researcher recruitment program enhances Texas' research capacity and is the envy of the rest of the nation. These recruits will be a major, if not the major legacy of CPRIT.
- Early translational research is the nexus between academic and product development research. Research kernels are identified and their practical viability proven through translation. This is the research "valley of death" - the place where good ideas die for lack of funding.
- Prevention and early detection span all three programs and are relatively underfunded by the National Cancer Institute (NCI) and others. Emphasizing them may be our greatest opportunity to reduce the burden of cancer.

Attachments or enclosures:

Attachment 1 - *Texas Cancer R&D Landscape: Optimizing CPRIT's Impact*

Attachment 2 - *Historical Funding Allocations*

Attachment 3 - *CPRIT's Program Priorities for 2016*

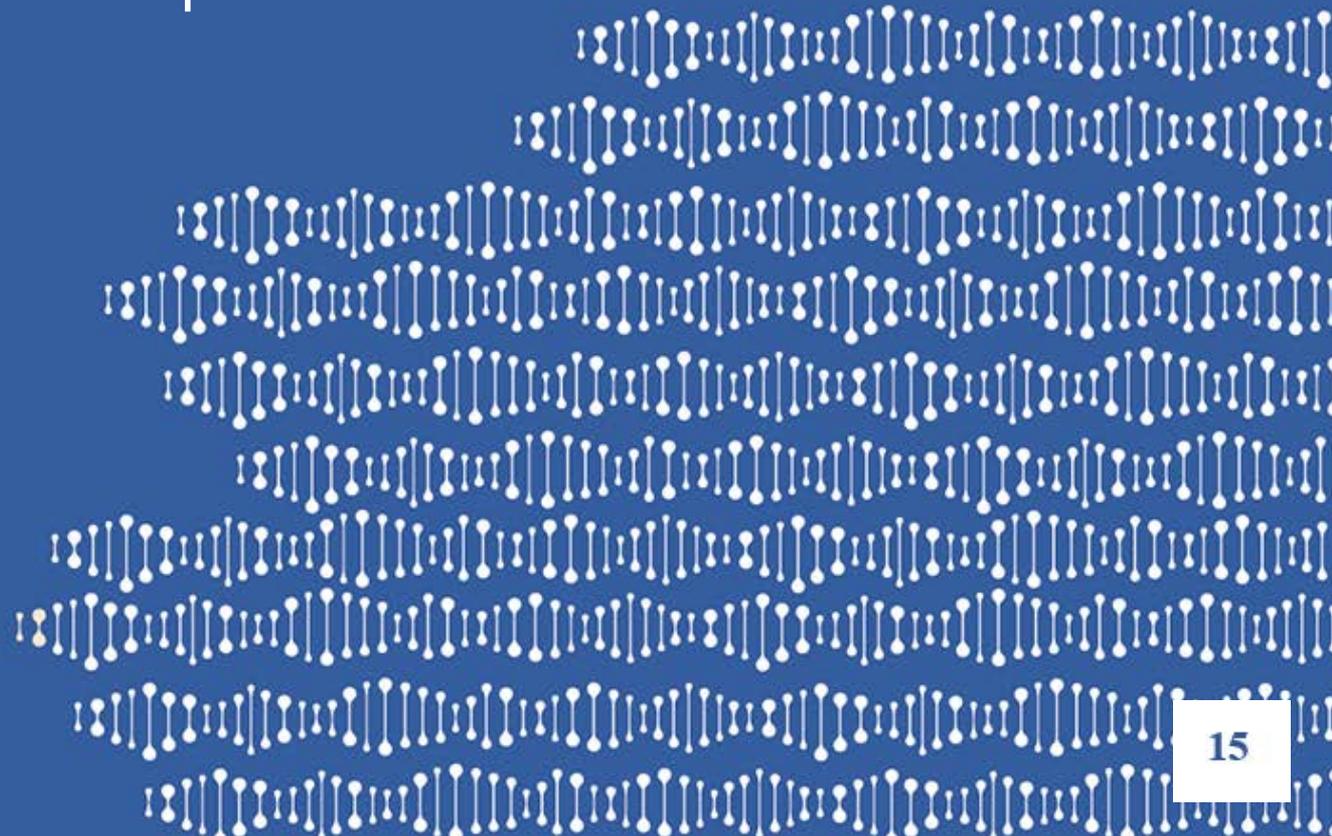
"CPRIT's Unique Role in Fighting Cancer" continuum



Texas Cancer R&D Landscape Optimizing CPRIT's Impact

May 19, 2016

Presented By:
Michael Lang



TX Health Care R&D Landscape

Contents

- TX Cancer Research and Development Landscape
- CPRIT Portfolio Overview
- Drug Development Overview
- Optimizing CPRIT's Impact



Cancer Research Funding – TX below US

NIH & NCI Research Grants	TX Research Grant Distribution
<p>NIH Grants – Life Sciences Research</p> <ul style="list-style-type: none"> Total \$22 B Texas \$980MM = <u>4.4% of US</u> <p>NCI Grants – Cancer Research</p> <ul style="list-style-type: none"> Total \$2.9 B Texas \$204 MM = <u>7.0 % of US</u> <p>TX Pop 27 MM = <u>8.4% of US Pop or 9.4% of GDP</u></p>	<ul style="list-style-type: none"> UT system = 62% of TX NIH grants Baylor College of Medicine = 14% of TX NIH grants UT + BCM = 76% of TX NIH grants MD Anderson = 50% of TX NCI grants
<p>TX share of health care and cancer research are below our share of US population and GDP</p>	



VC Life Sciences Funding – Texas Below US

Total VC Investment	Life Science VC Investment
<ul style="list-style-type: none"> • \$51 B Total VC Investments • \$1.31B Total TX VC Investments • TX = <u>2.8%</u> US VC investment <p>City Ranking among 40 largest MSA's</p> <ul style="list-style-type: none"> • Austin 5th of 40 (\$386 per capita) • Dallas 25th of 40 (\$31 per capita) • San Antonio 29th of 40 (\$23 per cap.) • Houston 31th of 40 (\$21 per capita) 	<ul style="list-style-type: none"> • \$9.4B Total VC life sciences • \$216MM TX VC life sciences • TX = <u>2.3%</u> US VC investment <p>Source Thompson Reuter and US Census (\$MM VC investment per capita MM)</p>
<p>TX share of VC investment is below our share of US population and GDP.</p>	



CPRIT has Significant Impact on TX Cancer R&D

		NIH & NCI Grants to Institutions	VC Investment in TX
	• Total NIH Grants	\$24B	<ul style="list-style-type: none"> • TX VC investment into Health Care \$216MM/yr. • CPRIT Prod Dev Funding =\$51MM
	• NIH- TX Research Grants Total	\$970MM	
	• NCI- TX Cancer Research Grants	\$204MM	
	• CPRIT Research Grants	\$204MM	
		<u>CPRIT Doubles TX Cancer Research</u>	<u>CPRIT Increases TX VC Investment into Health Care by 25%</u>

CPRIT has significant impact.



University Research & Spinouts

University Research = \$65 B

- Most federally funded
- Most life sciences & defense

Top 100 US Research Universities

3 + years of Research

Knowledge

- In public domain
- Value not quantifiable

Commercialization

- Patents licensed to existing firms
- Startup companies per year- 751
- R&D expenditure per startup = \$88 MM
- UT R&D expenditure per startup = \$95 MM

Why is Research Spend per Startup so High?

- Funding supports both basic and applied science. Only applied science is commercially relevant.
- Research sometimes not aligned with clinical needs.
- University research not verified; sometimes can't be replicated.
- Limited commercialization focus and resources at University Tech Transfer Offices..



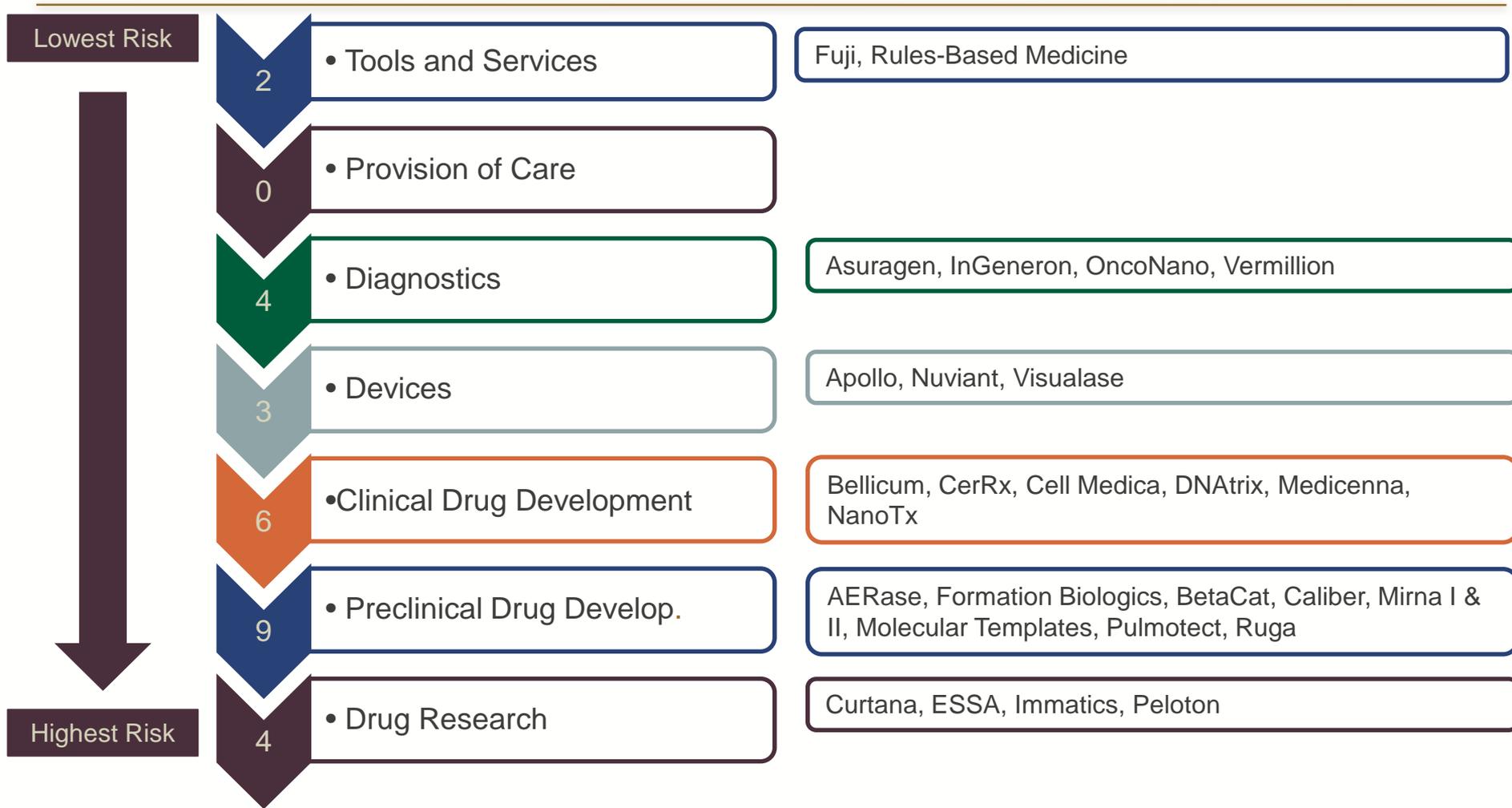
TX Life Sciences R&D Landscape

Contents

- TX Cancer Research and Development Landscape
- CPRIT Portfolio Overview
- Drug Development Overview
- Optimizing CPRIT's Impact



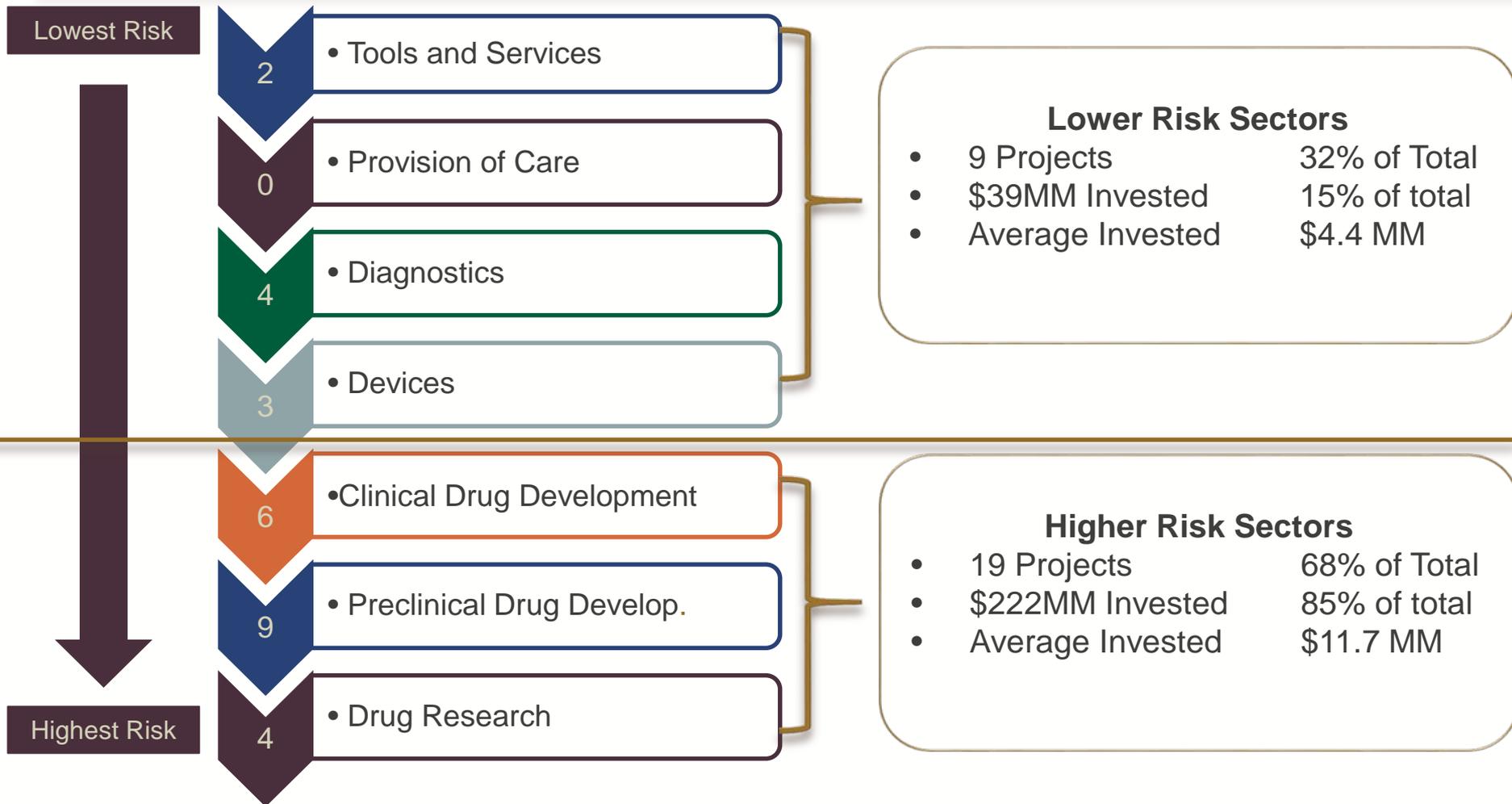
CPRIT Portfolio is in High Risk Sectors



28 Investments; 19 in Oncology Drug Development (High Risk) & 9 in Other Sectors (Lower Risk)



CPRIT Portfolio – 85% Oncology Drugs



CPRIT predominantly invested in oncology drug development.



Optimizing CPRIT's Product Development Impact

Contents

- TX Cancer Research and Development Landscape
- CPRIT Portfolio Overview
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Drug Development Process Overview



Drug Development Process Details

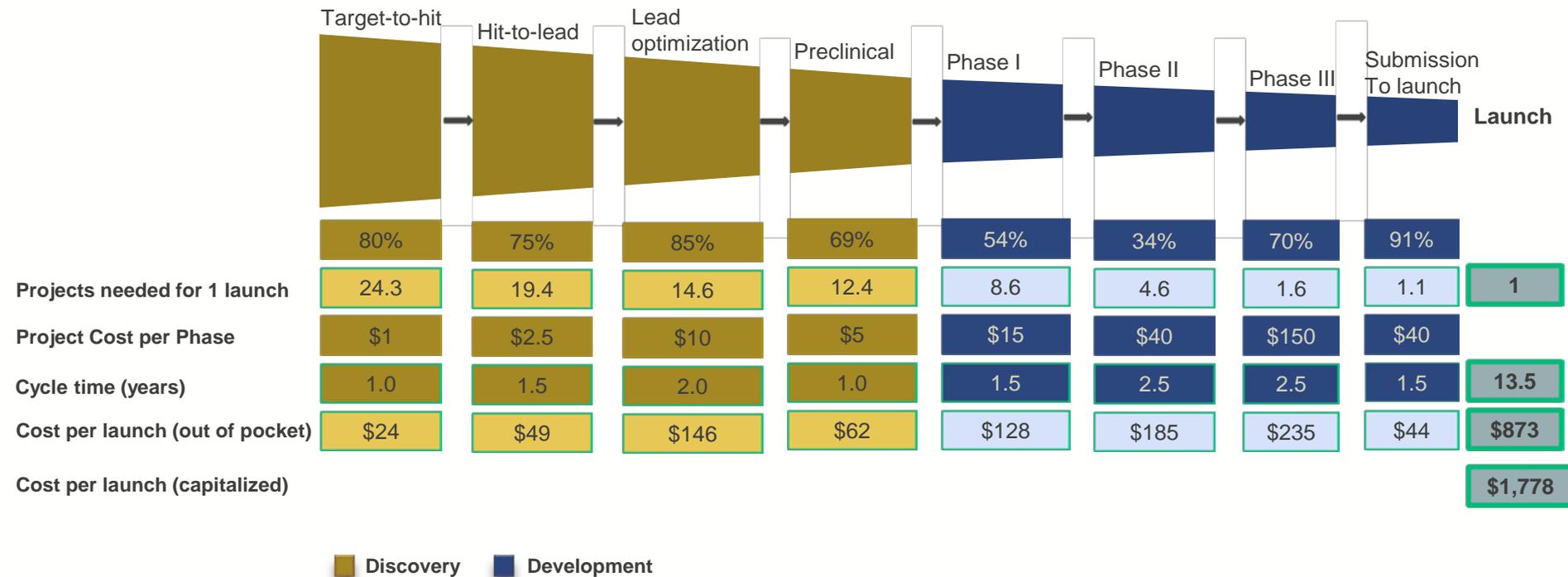
Academic Research Basic & Applied			Licensing & Newco	Compound Develop. BioTech Co.	Clinical / Reg. Big Pharma
Stage	Basic Research	Applied Research	Newco Spinout	Compound Development	Clinical Development and Regulatory
Objective	Understand Disease Biology	Do Something New (Target ID)	Form Newco to Develop Drug	Find, Optimize, Validate Lead Compounds	Confirm Safety, Efficacy & Regulatory Approval
Who	Academic R&D	Academic R&D	Tech Transfer & Entrepreneur	BioTech Startups	Phase 1 & 2 – BioTechs Phase 3 & Regulatory- Big Pharma
Funding	NIH Grants	Most from NIH – Rest Company & philanthropy	Seed Funding	VCs	VCs and Big Pharma

CPRIT Research Grants = 80% of \$'s

CPRIT Product Development Grants = 20% of \$'s



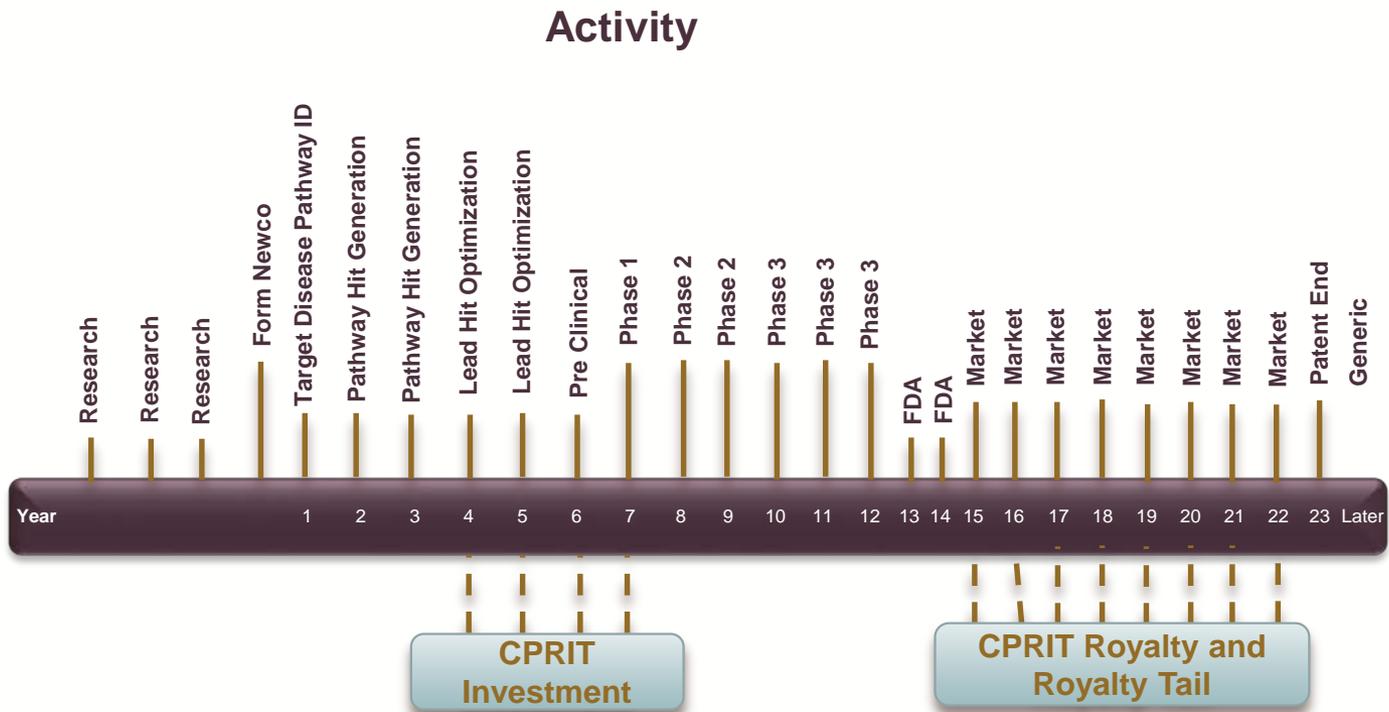
Drug Development is High Risk and Cost



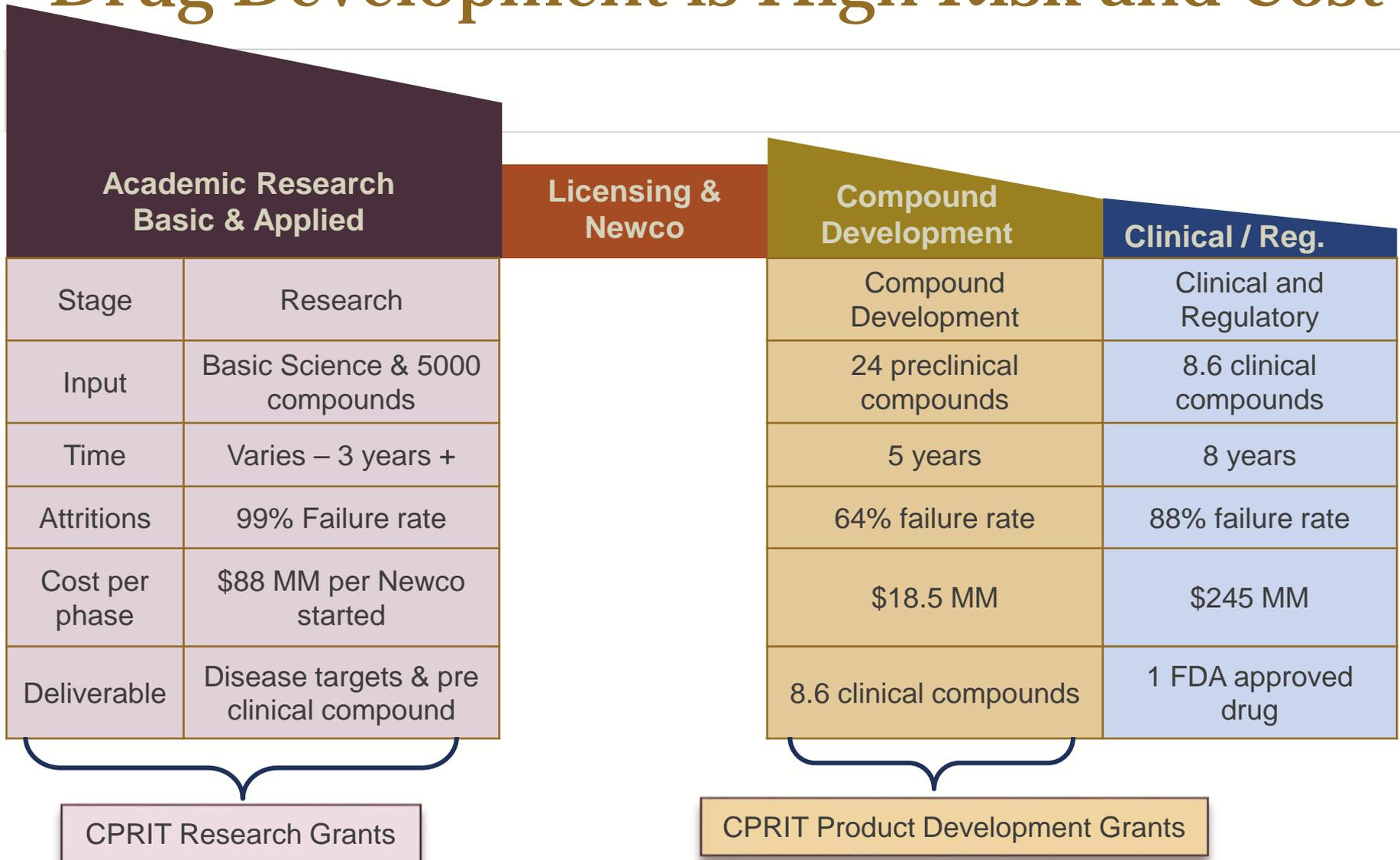
Long development cycle (13 years)
High attrition (1 in 24 succeed)
High cost (\$2 BB per new drug)



Drug Life Cycle



Drug Development is High Risk and Cost



Oncology Drug Market Notes

Oncology Drug Market

- \$100 B market
- Typical annual revenue an patented cancer therapeutic = \$1/2 B to \$5 B
- Top selling drugs generate up to \$8 B revenue
- Oncology = 10% of Pharma industry
- Typical oncology drug cost = \$20,000 per patient monthly for 9 months
- 50% is targeted therapeutics

US Cancer Annual Incidence = 1.66 MM
5 Cancers account for 60% of diagnoses

Oncology Drug R&D

- 1800 Cancer drugs in development
- 1000 cancer clinical studies ongoing
- 30 New drugs approved in 2014 (up from historical average)
- Pharma industry R&D = \$65B annually
- NIH grants = \$24B annually
- VCs invested \$22B in cancer drugs since 1980

Breast	234,000
Colorectal	133,000
Lung	221,000
Prostate	221,000
Skin	159,000



Optimizing CPRIT's Product Development Impact

Contents

- TX Cancer Research and Development Landscape
- CPRIT Portfolio Overview
- Drug Development Overview
- Optimizing CPRIT's Impact



Clinical Impact of \$1 BB Investment

Basic & Applied Research		Licensing & Newco	Compound Development		Clinical / Reg.	
Academic Research			Compound Development		Phase I & II Clinical Trial	
Project Cost	\$1.3 M		Project Cost	\$18.5 M	Project Cost	\$55 MM
Project Starts	780		Project Starts	54	Project Starts	18
Output	14 Newcos		Output	19 Compounds	Output	3.3 Drugs
Attrition	1:24		Attrition	1:8.6	Attrition	1:1.6
Results	0.6 Drug + Publication & knowledge		Results	2.2 New Drugs	Results	2.1 New Drugs



CPRIT Product Dev.– Principles & Priorities

Principles

- “Improve Patient care through expedited innovation & product development”
- “Catalyze economic development in TX’s emerging life sciences industry”
- “Provide direct return, through IP and revenue sharing, on investments”

OC Program Priorities

- Fund projects most likely to bring important projects to market
- Promote translation of research at TX institutions into new companies
- Identify projects to develop technologies with special relevance to cancer

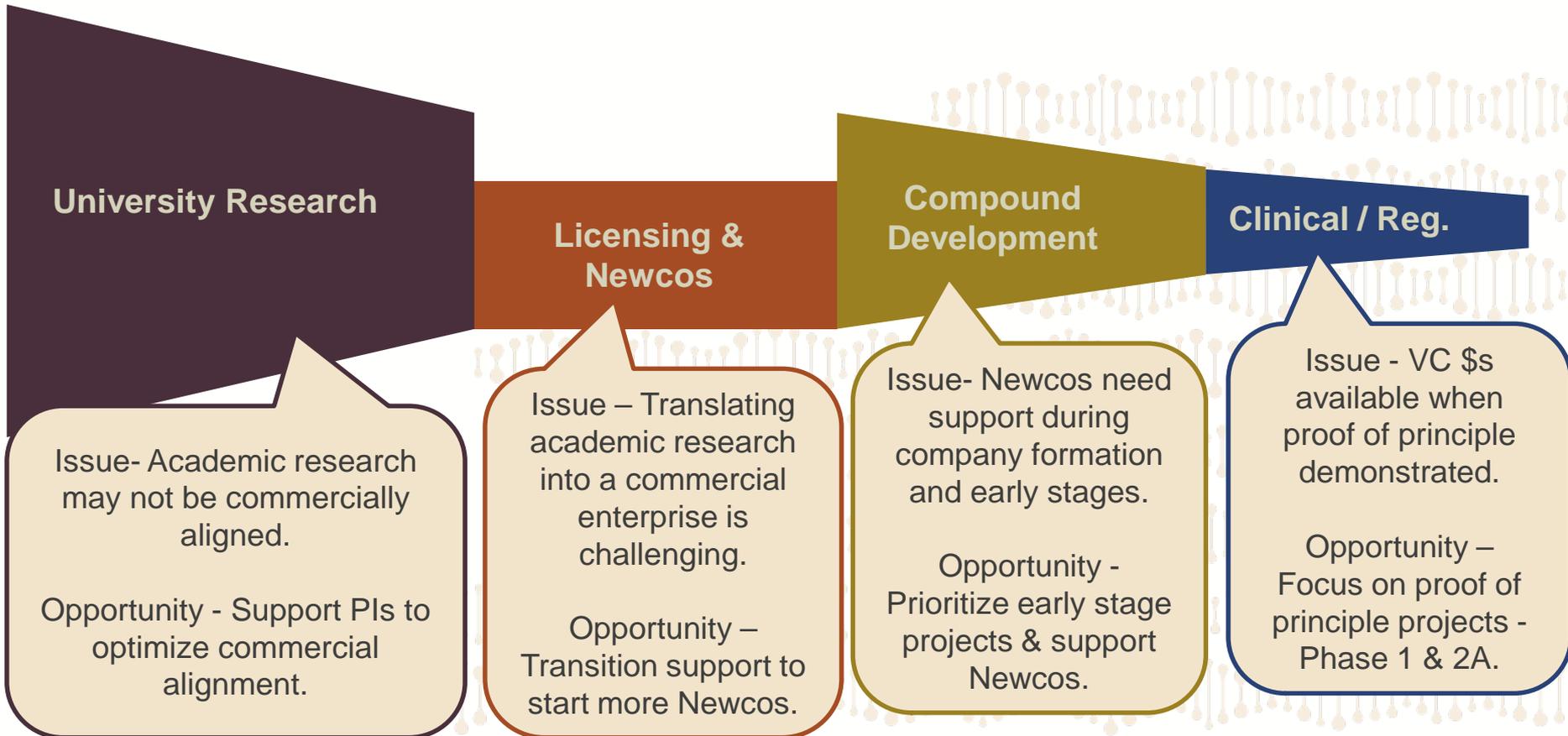


Drug Development Process Key Issues

Basic & Applied Research		Licensing & Newco	Compound Develop.	Clinical / Reg.	
	Basic Research	Applied Research	Newco Spinout	Compound Development	Clinical Development and Regulatory
Issues	<ul style="list-style-type: none"> • “Publish or perish” -impacts outputs • Linkage to clinical needs • Hard to fund research outside of traditional interests 	<ul style="list-style-type: none"> • “Publish or perish” - impacts outputs • Limited verification & replication of outputs 	<ul style="list-style-type: none"> • “Valley of death” funding gap • Challenging process • Limited seed funds 	<ul style="list-style-type: none"> • High attrition rate • Expensive FDA-mandated process (Costs = \$18.5 MM per compound) • Specialized services outsourced 	<ul style="list-style-type: none"> • Expensive FDA-mandated process (Cost = \$245 MM per compound) • Typically Big Pharma buys compound and conducts Phase 3 trials • Dynamic regulatory and payer environment



Enhancing CPRIT's Impact



CPRIT Portfolio Includes All Stages

Basic & Applied Research	Licensing & Newco	Compound Development	Clinical / Reg.
Stage	Newco	Development & Clinical	Mature
Definition	Only CPRIT or Angel Investors	Have raised VC Investment	Public or Profitable
Management and BoD	Incomplete Mgmt. & BoD	Mgmt. & BoD in place	Mgmt. & BoD in place
Other Support Required	Strategy, Connectivity	Typically None	None
Portfolio Company Classifications	Curtana, OncoNano, BetaCat, NanoTx, Formation Biologics	AERase, Vermillion, Nuviant, Medicenna, Pulmotect, Molecular Templates, ESSA, Immatic	Asuragen, Mirna, Cell Medica, CerRx, DNatrix,

Investor engagement may be required to optimize performance. Consider enhanced CPRIT Support

VC's & BoD likely providing required oversight

VC's & BoD likely providing required oversight



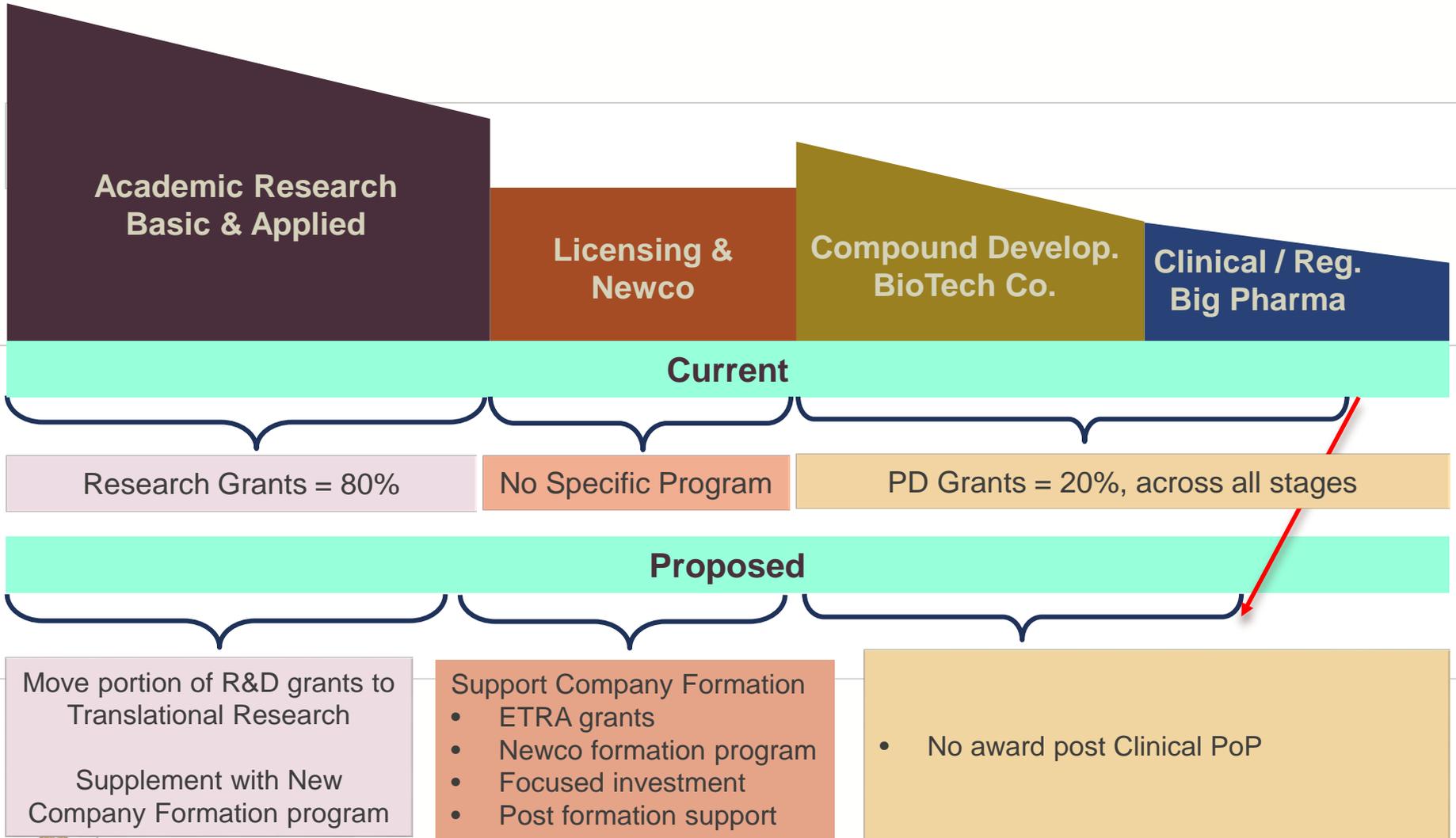
Policy and Strategy Proposals

Product Development Opportunities

- Investment by Stage of Company Development
- New Company Formation
- Support Early Stage Firms



Summary of Proposals



Investment Policy – Stage of Development

Issue and Status

Issue

- CPRIT is stage agnostic, investing at all stages of drug development; drug research, compound development, preclinical testing, initial clinical trials, later stage clinical trials.
- Should we focus or avoid investing at certain stages?

Discussion Status

- Reviewed with OC and PDRC
- Consensus that early stage is most compatible with CPRIT mission
- However, high risk of early stage investments may be difficult for external constituencies to understand.

Proposal and Rationale

Proposal

- Invest prior to initial clinical Proof of Principle only (i.e. drug research, compound development, preclinical testing, initial clinical trials).
- Companies with good clinical data can access VC or public market money.
- Investment in public companies not consistent with our mission as they can access VC or public market money.

Rationale

- Optimizes TX economic impact
- Maximizes university spinouts
- Company with good clinical data can access VCs or public market money.



Product Dev. Strategy– Newco Formation

Issue and Status

Issue

- New company formation and launch is synergistic with CPRIT mission
- No specific CPRIT support for Newco formation today

Discussion Status

- Discussed with OC
- MD Anderson and UT express interest
- Need to assess interest from other TX institutions
- More in-depth discussions with institutions and further assessment required.

Proposal and Rationale

Proposal

- Develop commercialization programs with interested applicable institutions
- Insure support infrastructure in place (program mgmt., EIRs, services etc.).
- CPRIT support of program overhead, EIR's, and proto-company formation costs TBD

Rationale

- Address significant gap in commercialization process
- Enhances TX economic impact
- Enhances clinical and economic benefits from R&D investment
- Enhances PI retention
- Attracts industry talent and VCs to TX



Product Dev. Strategy– Support Early Startups

Issue and Status

Issue

- Some CPRIT grants are provided to Newcos without full management team and Board of Directors
- Company leadership may not have external guidance which could impact performance
- Few proto-companies in this category

Discussion Status

- Reviewed briefly with OC

Proposal and Rationale

Proposal

- Dedicated support to proto-companies via BoD observer role until professional money invested
- BoD observer can be PDRC member, Chief Product Development Officer or contracted external support

Rationale

- Increases probability of success with minimal costs
- Number of proto-companies will increase if we focus on Newco formation
- Insure COI issue is fully vetted



Cumulative Academic Research Funding by Mechanism and Financial Year																
May 10, 2016																
(Dollars in Millions)																
Mechanism	FY10		FY11		FY12		FY13		FY14		FY15 ¹		FY16		Mechanism Totals	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Bridging the Gap: Early Translational Research Awards	-	\$ -	-	\$ -	9	\$ 8.3	-	\$ -	-	\$ -	20	\$ 33.9	-	\$ -	29	\$ 42.1
Core Facility Support Awards	-	\$ -	-	\$ -	8	\$ 25.5	3	\$ 11.7	-	\$ -	6	\$ 30.9	-	\$ -	17	\$ 68.2
High Impact/High Risk	14	\$ 2.8	12	\$ 2.4	12	\$ 2.4	14	\$ 2.8	15	\$ 3.0	16	\$ 3.2	-	\$ -	83	\$ 16.5
Individual Investigator	60	\$ 65.8	43	\$ 37.5	44	\$ 43.6	44	\$ 42.8	60	\$ 50.4	36	\$ 31.4	39	\$ 34.7	326	\$ 306.0
Individual Investigator Research Awards for Cancer in Children and Adolescents	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	10	\$ 18.0	5	\$ 6.1	15	\$ 24.1
Individual Investigator Research Awards for Computational Biology	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	1	\$ 0.4	1	\$ 0.4
Individual Investigator Research Awards for Prevention and Early Detection	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	5	\$ 5.9	6	\$ 6.6	11	\$ 12.5
Multi-Investigator	59	\$ 56.5	66	\$ 86.9	41	\$ 39.4	-	\$ -	26	\$ 11.1	2	\$ 15.9	-	\$ -	194	\$ 209.9
Research Training	7	\$ 17.7	-	\$ -	-	\$ -	-	\$ -	7	\$ 11.8	-	\$ -	4	\$ 15.0	18	\$ 44.4
Shared Instrumentation Awards	-	\$ -	5	\$ 9.5	3	\$ 3.0	-	\$ -	-	\$ -	-	\$ -	-	\$ -	8	\$ 12.4
Non-Recruitment Award Totals:	140	\$ 142.8	126	\$ 136.2	117	\$ 122.2	61	\$ 57.3	108	\$ 76.3	95	\$ 139.2	55	\$ 62.8	702	\$ 736.7
Recruitment of Established Investigators	1	\$ -	5	\$ 35.0	6	\$ 36.5	2	\$ 7.2	3	\$ 18.0	4	\$ 22.0	5	\$ 30.0	26	\$ 148.7
Recruitment of First-Time, Tenure-Track Faculty Members	6	\$ 12.0	10	\$ 20.0	15	\$ 28.8	2	\$ 4.0	16	\$ 31.8	13	\$ 27.0	7	\$ 14.0	69	\$ 137.6
Recruitment of Missing Links	-	\$ -	3	\$ 5.9	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	3	\$ 5.9
Recruitment of Rising Stars	2	\$ 8.0	1	\$ 2.0	1	\$ 4.5	2	\$ 5.2	2	\$ 6.5	-	\$ -	4	\$ 15.7	12	\$ 42.0
Recruitment Award Totals:	9	\$ 20.0	19	\$ 62.9	22	\$ 69.8	6	\$ 16.4	21	\$ 56.3	17	\$ 49.0	16	\$ 59.7	110	\$ 334.2
Award Totals:	149	\$ 162.8	145	\$ 199.1	139	\$ 192.0	67	\$ 73.8	129	\$ 132.6	112	\$ 188.2	71	\$ 122.5	812	\$ 1,070.9

¹ FY15 Bridging the Gap: Early Translational Research Awards were reviewed under the Product Development program.

**Cumulative Product Development Research Funding by Mechanism and Financial Year
May 10, 2016**

(Dollars in Millions)

Mechanism	FY10		FY11		FY12		FY13		FY14		FY15		FY16		Mechanism Totals	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Company Recruitment	1	\$ 11.0	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	1	\$ 11.0
Company Relocation	-	\$ -	-	\$ -	1	\$ 15.6	-	\$ -	1	\$ 12.0	-	\$ -	-	\$ -	2	\$ 27.6
Established Company	5	\$ 20.7	1	\$ 5.7	3	\$ 30.2	-	\$ -	3	\$ 47.4	1	\$ 7.5	-	\$ -	13	\$ 111.5
New Company	-	\$ -	-	\$ -	2	\$ 15.0	-	\$ -	4	\$ 35.5	5	\$ 49.5	1	\$ 20.0	12	\$ 120.0
Award Totals:	6	\$ 31.7	1	\$ 5.7	6	\$ 60.8	-	\$ -	8	\$ 94.9	6	\$ 57.0	1	\$ 20.0	28	\$ 270.2

Cumulative Prevention Funding by Mechanism and Financial Year

May 10, 2016

(Dollars in Millions)

Mechanism	FY10		FY11		FY12 ¹		FY13		FY14		FY15		FY16		Mechanism Totals	
	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount	No.	Amount
Cancer Prevention Microgrants	-	\$ -	5	\$ 0.9	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	5	0.9
Cancer Prevention Promotion and Navigation to Clinical Services	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	2	\$ 0.8	2	0.8
Community Collaborative Prevention Programs and Services	4	\$ 6.7	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	4	6.7
Competitive Continuation/Expansion - Education	-	\$ -	-	\$ -	-	\$ -	-	\$ -	2	\$ 0.3	-	\$ -	-	\$ -	2	0.3
Competitive Continuation/Expansion - Evidence-Based Services	-	\$ -	-	\$ -	-	\$ -	-	\$ -	7	\$ 9.5	6	\$ 9.0	4	\$ 5.5	17	24
Dissemination of CPRIT-Funded Cancer Control Interventions	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	2	\$ 0.6	2	0.6
Education	20	\$ 6.1	20	\$ 7.7	5	\$ 1.7	-	\$ -	2	\$ 0.6	-	\$ -	-	\$ -	47	16.1
Evidence-Based Cancer Prevention Services	6	\$ 5.1	10	\$ 13.1	21	\$ 40.8	-	\$ -	14	\$ 17.9	8	\$ 11.5	3	\$ 4.1	62	92.5
Evidence-Based Cancer Prevention Services - Colorectal Cancer Prevention Coalition	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	2	\$ 7.4	1	\$ 2.3	3	9.7
Innovation Awards for Cancer Prevention Programs and Services	1	\$ 0.1	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	1	0.1
Legacy Grant	13	\$ 3.6	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	-	\$ -	13	3.6
Award Totals:	44	\$ 21.7	35	\$ 21.7	26	\$ 42.5	-	\$ -	25	\$ 28.3	16	\$ 27.9	12	\$ 13.2	158	155.4

¹ 14 Grants Approved on 8/2/2012:

- 2 Grants (\$2.6) funded from FY12 Funds
- 12 Grants (\$13.6) funded from FY13 Funds



**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
PROGRAM PRIORITIES FOR 2016**

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ABOUT CPRIT PROGRAM PRIORITIES PROJECT

CPRIT is governed by Health and Safety Code: Chapter 102. Legislation from the 83rd Texas Legislature modified that code to include enhancements to CPRIT's governance and operations. One of the specific enhancements requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

The Oversight Committee priorities are to be reviewed and adjusted annually as circumstances change and new information is found concerning cancer-related advances in prevention, academic research and product development research

CPRIT Purpose

Health and Safety Code: Chapter 102

Sec. 102.002. PURPOSES. The Cancer Prevention and Research Institute of Texas is established to:

- (1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- (2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
- (3) develop and implement the Texas Cancer Plan.

Program Priorities Legislative Mandate

Health and Safety Code: Chapter 102

Sec. 102.107. POWERS AND DUTIES. The oversight committee shall:

- (1) hire a chief executive officer;
- (2) annually set priorities as prescribed by the legislature for each grant program that receives money under this chapter; and
- (3) consider the priorities set under Subdivision (2) in awarding grants under this chapter.



PROCESS TO DEVELOP PROGRAM PRIORITIES

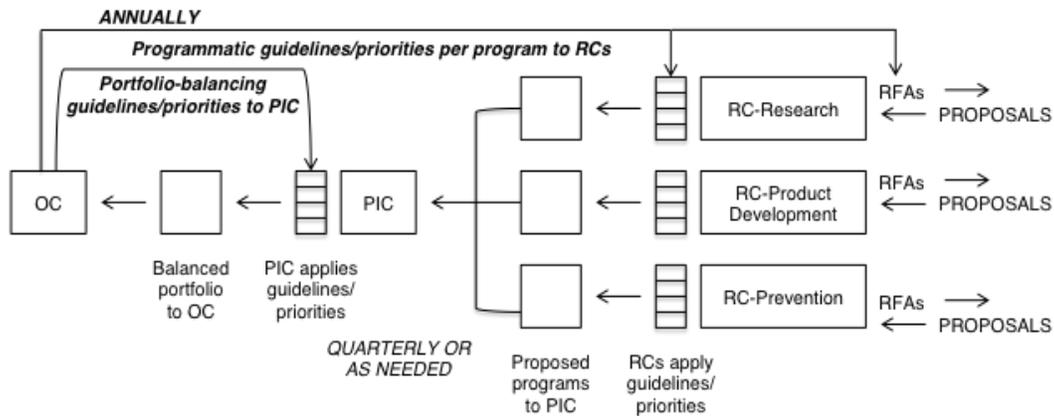
The Oversight Committee approved the 2015 program priorities on November 19, 2014 after a six month process that included subcommittee meetings and public input. The program priorities were subsequently incorporated into the requests for applications released by each program. In August 2015, the Academic Research, Product Development Research and Prevention Oversight Committee Subcommittees reviewed the 2015 program priorities and determined that no changes to the priorities were needed for 2016. Their recommendations were presented at the Oversight Committee meeting on November 19, 2015.

SCOPE OF PROGRAM PRIORITIES PROJECT

The Program Priorities Project establishes priorities at two levels of CPRIT’s grant making process:

- **Priorities Within Each of CPRIT’s Programs** – priorities to inform staff and respective Peer Review Councils (RCs) on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications submitted in response to those RFAs.
- **Priorities Across CPRIT’s Three Programs** – priorities to inform the Program Integration Committee (PIC) on balancing the portfolio across the research, prevention and product development programs.

Priorities and CPRIT’s Grant Making Process





CPRIT'S LONG-TERM VISION

As the Oversight Committee set out to establish program priorities, it began by defining the long-term vision for the agency and each of the three programs in alignment with CPRIT's mandated purpose.

Innovative projects funded by CPRIT will result in:

- A decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products;
- A recognition of and focus on disparities in cancer incidence, mortality and access to care;
- Significant advancements in the scientific understanding of cancer; and
- An enhanced and expanded life sciences infrastructure in the state as a result of recruiting researchers, training health care/science professionals, attracting companies and supporting investigator startups.

PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

Priorities within each of CPRIT's programs –academic research, prevention and product development research– will inform staff and respective Peer Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications to those RFAs.

CPRIT's three programs are currently guided by established key principles essential to executing CPRIT's purpose. The main principle underlying all three programs is that they will continue to ensure only applications with scientific merit will move forward in CPRIT's peer review grant process. In addition, the programs have established principles that are unique to each program. The new program priorities will supplement these principles to guide the selection of meritorious applications to address CPRIT's strategic priorities as set annually by the Oversight Committee.

*It is important to note that these priorities **do not** exclude funding in areas outside of the identified priorities.*

Academic Research Program

Background: The goal of CPRIT's academic research program is to discover new information about cancer that can lead to prevention, early detection, and more effective treatments; translate new and existing discoveries into practical advances in cancer diagnosis, treatment, and survivorship; and increase the prominence and stature of Texas in the fight against cancer. Until now, CPRIT's strategy has been to support the most creative ideas and the most meritorious projects brought forward by the cancer research community in Texas. Going forward, the overarching principles for awarding CPRIT funds will continue to be scientific excellence and impact on reducing the burden of cancer. However, more strategic deployment of funds is



intended to accelerate progress in cancer research beyond what can be achieved by simply adding incrementally to the types of cancer research funded by other agencies.

Therefore, CPRIT's academic research program will seek to fund projects in critical, but underfunded areas of cancer research, in addition to funding investigator-initiated, untargeted proposals. Areas of opportunity for strategic deployment of funds include prevention and early detection research; computational biology and analytic methods; rare cancers, particularly pediatric tumors, and intractable cancers, including lung, liver, pancreatic and brain cancers, with particular emphasis on population disparities and cancers of significance in Texas

Finally, it is critically important to add to the life sciences infrastructure in the State of Texas. This will enable CPRIT's impact on cancer research to extend for years beyond the lifetime of the program. Most important to increasing infrastructure is the recruitment of preeminent researchers. Such individuals bring additional resources to the State, including research funding and new expertise, as well as help build the critical mass of science needed to attract investments in the development of products for cancer prevention, diagnosis, and treatment. Also critical are the training programs that aim to produce the next generation of cancer researchers and increase the diversity of the cancer research workforce.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

Academic Research Program Priorities
<ul style="list-style-type: none">• A broad range of innovative, investigator-initiated research projects• Prevention and early detection• Computational biology and analytic methods• Rare and intractable cancers, including childhood cancers• Population disparities and cancers of importance in Texas• Recruit outstanding cancer researchers to Texas



Prevention Program

Background: The following principles have guided the prevention program since its inception in 2009. These principles have informed the development of the requests for applications (RFAs) and the evaluation of applications submitted in response to the RFAs.

Through the prevention program, CPRIT seeks to fund projects that:

- Are evidence based – offering effective prevention interventions based on the existing body of knowledge about and evidence for cancer prevention.
- Deliver primary, secondary, or tertiary (includes survivorship) prevention interventions – providing state of the art preventive clinical services and tailored, culturally appropriate, and accurate information to the public and health professionals.

In addition, the program has focused on providing access to underserved populations and serving the populations in most need including underinsured and uninsured individuals and those disproportionately affected by cancer.

In order to achieve some degree of balance to the prevention program portfolio, the Prevention Review Council (PRC) conducts a programmatic review of applications under consideration. During programmatic review, the Prevention Review Council (PRC) evaluates applications judged to be meritorious by prevention review panels. Programmatic considerations include:

- Potential for impact
- Geographic distribution
- Cancer type
- Type of program or service

While these principles provide guidance for the program, identifying priorities based on areas where significant cancer incidence and mortality disparities exist focuses the program further on areas of greatest need and greatest potential for impact.

Data on cancer incidence, mortality and disparities (geographic, ethnic, etc.) are reviewed annually to identify priorities and identify areas of emphasis. This information informs the development of RFAs and informs programmatic decisions during the PRC level of review.



Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities
<ul style="list-style-type: none">• Prioritize populations and geographic areas of greatest need, greatest potential for impact• Focus on underserved populations• Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

Product Development Research

Background: CPRIT’s product development program should:

- **Identify private sector entities to develop products that will benefit cancer patients –** Gaps exist in the market’s ability to translate research insights and product visions into FDA approved and commercially available products. These gaps may delay, or even deny, cancer patient access to important scientific advances. CPRIT should work to bridge these gaps, leveraging its funds with matching funds from other sources.
- **Selectively deploy its resources where they are most needed and can do the most good –** There are more scientifically and commercially sound product development opportunities than CPRIT is capable of funding. Thus, CPRIT should:
 - Fund commercial projects that might be “game changing” or disruptive;
 - Attract and support cancer-related life sciences companies that will create jobs in Texas;
 - Attract matching funds and additional investments from other sources; and
 - Act in conjunction, but not in competition, with private funding sources or other governmental funding sources.



Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of cancer patients
- Creation of good, high-paying jobs for Texans
- Sound financial return on the monies invested
- Development of the Texas high tech life sciences business environment

Product Development Research Program Priorities

- Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market
- Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace
- Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention

PRIORITIES ACROSS CPRIT’S THREE PROGRAMS

Establishing priorities across CPRIT’s research, prevention and product development programs will inform the Program Integration Committee (PIC) on balancing the portfolio across the three programs.

CPRIT’s structure, which includes programs in research, prevention and product development, presents a unique opportunity for funding projects that span the continuum from discovery to delivery to the public and creating synergy across the spectrum. While CPRIT programs would continue to fund a broad range of programs and cancer types, selecting areas of emphasis where CPRIT could have an impact and distinguish it from other funding sources provides a basis for focusing resources and guiding decisions when resources are limited. The recommended areas of emphasis outlined below also correspond to unmet needs – places in the cancer research and care continuum where existing institutions have not provided strong programs or results.

It is important to note that these priorities serve as strategic areas of emphasis and do not exclude funding in areas outside of the identified priorities.



Prevention and Early Detection Initiatives

Rationale: Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This spares people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer therapies, and the financial burden associated with cancer treatment. In addition, the current emphasis in cancer research on finding cures for advanced cancers has serious limitations. Thus far, attempts to control cancer by chemotherapy, radiation, and even targeted therapy have been thwarted by the ability of cancer cells to develop resistance to these treatment modalities. Detecting cancer early in its development is a more desirable approach to cancer control. In spite of the potential impact of prevention and early detection on reducing the cancer burden, these areas of cancer research receive little funding relative to funding devoted to curing advanced cancer.

Emphasis: Ideally, academic research would create the evidence base for new approaches to prevention and early detection, product development research would provide new methods, diagnostics, imaging or devices for early cancer detection, and the prevention program would implement interventions to put these new approaches into practice once a solid evidence base of effectiveness exists. Strategies would include each program issuing either a targeted RFA or listing prevention or early detection as an area of emphasis (among others) within current RFAs. In addition, the programs can explore RFAs that could span programs, e.g. RFAs that would support a research component to a prevention project.

Early Translational Research

Rationale: One well-documented impediment to bringing the results of basic research to bear on cancer is the shortage of funding to translate new discoveries into practical advances for cancer patients. Research and development are needed between the stages of discovery science, traditionally funded by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals traditionally funded by private sector industries. Data indicate that such translational research is underfunded and would benefit from additional investment. Funding such research and development by CPRIT could have the added benefit of stimulating public-private partnerships and bringing new commercial investments to Texas.

Emphasis: Funding translational research that bridges the gap between basic research and product development, and between research on preventive measures and new technologies for early detection and on adaptation of tested interventions represents opportunities for inter-program strategic investment by CPRIT. The time needed to move some projects from research to products is often lengthy and may limit the role of the prevention program in this area of emphasis.



Enhance Texas' Research Capacity and Life Science Infrastructure

Rationale: CPRIT's statute emphasizes enhancing research superiority, increasing applied science and technology research capabilities and increasing high-quality jobs in the state. All three programs contribute to enhancing the research, life science and cancer control workforce and infrastructure in the state.

Emphasis: Establishing a critical mass of cancer researchers in Texas is possible by supporting the recruitment of cancer scientists and clinicians, at all career levels, to academic institutions in Texas and through training programs in which pre- and post-doctoral fellows are educated to become cancer researchers. The recruitment program has been successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in the medical and scientific communities.

CPRIT's investments in product development help to build Texas' life-science industry. While bringing a product to market can take time, jobs and economic activity are generated throughout the process. Every CPRIT award includes intellectual property requirements that specify a revenue return to Texas through the successful development of CPRIT-funded drugs, devices, diagnostics or services.

The prevention program supports the education and training of health care professionals and community workers, thereby increasing the state's capacity for cancer prevention and control activities. By requiring collaborative partnerships, the program also creates incentives for organizations and individuals to collaborate to tackle community problems through networks that can mobilize resources and avoid duplication of efforts. Implementing system changes (such as reducing wait times between screening and diagnostics, implementing patient reminder systems) by CPRIT funded programs also improves the infrastructure for the delivery of preventive interventions.



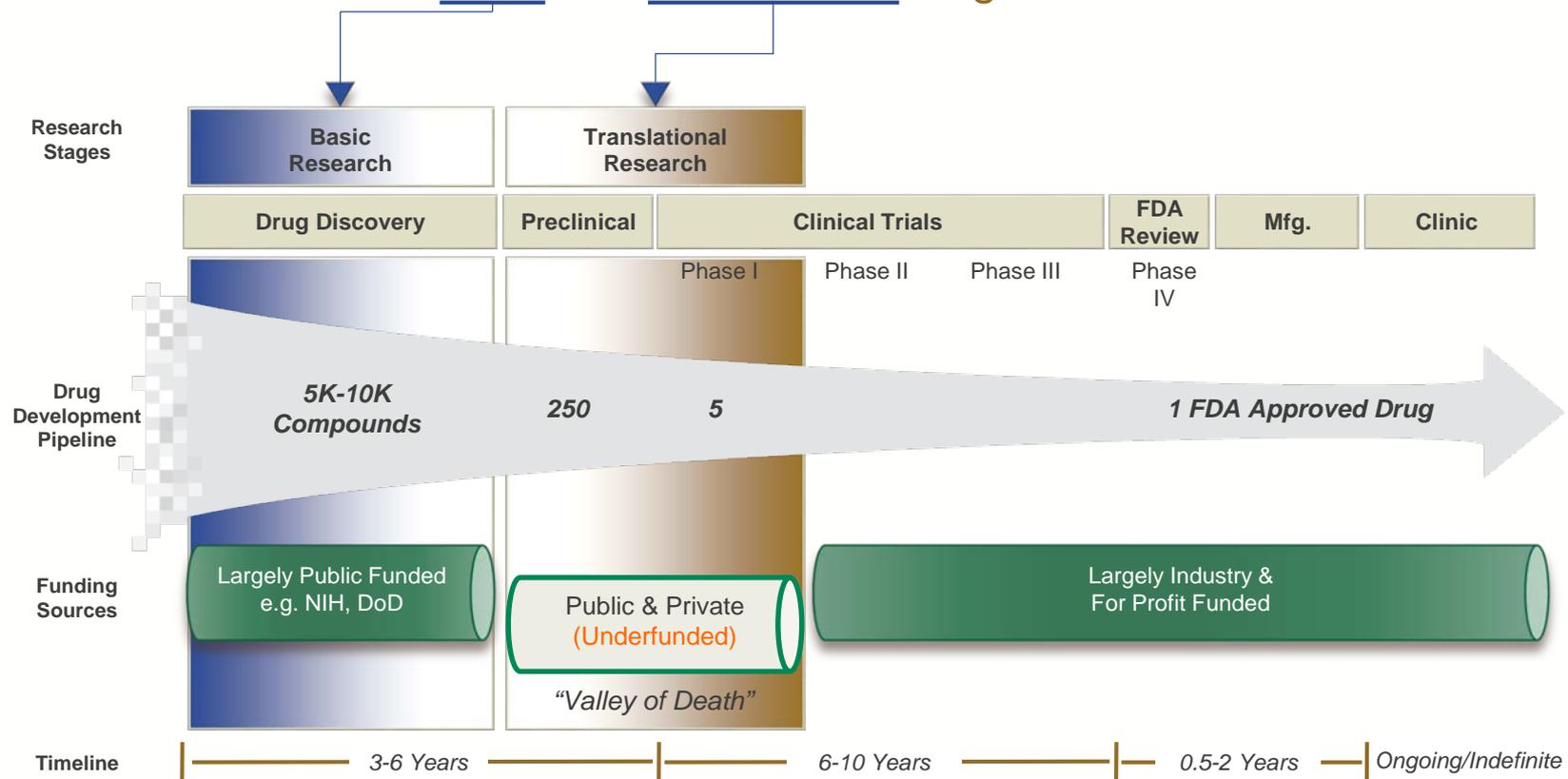
Summary: Priorities across CPRIT’s Three Programs

Below is a table summarizing how each of CPRIT’s three programs would implement the recommended areas of emphasis outlined above.

	Prevention and Early Detection Initiatives	Early Translational Research	Enhance Texas’ Research Capacity and Life Science Infrastructure
Academic Research Program Implementation	Create the evidence base for new approaches to prevention and early detection.	Identify CPRIT funded basic research that could translate new discoveries into practical advances.	Increase workforce and infrastructure: researcher recruitment, training grants and core facilities.
Prevention Program Implementation	Implement programs to put these new approaches into practice and continue to fund what is known to work (evidence based).	Due to long lead-time to product development, there may be limited role for prevention to implement programs resulting from this research.	Implementing systems change, developing partnerships and collaborations, training of community and healthcare providers, and creating new jobs.
Product Development Research Program Implementation	Fund new tools, technologies, methods and devices for early cancer detection and prevention.	Fund translational research that bridges the gap between basic research and product development.	Build up life sciences infrastructure and industry in Texas and create new high paying jobs.

CPRIT's Unique Role in Fighting Cancer

CPRIT focuses on the basic and translational stages of cancer research.



Average cost for approved drug: \$1 Billion

General timeframe to approved drug: 10-15 years



CPRIT's Unique Role in Fighting Cancer

Product Development Drug Life Cycle

