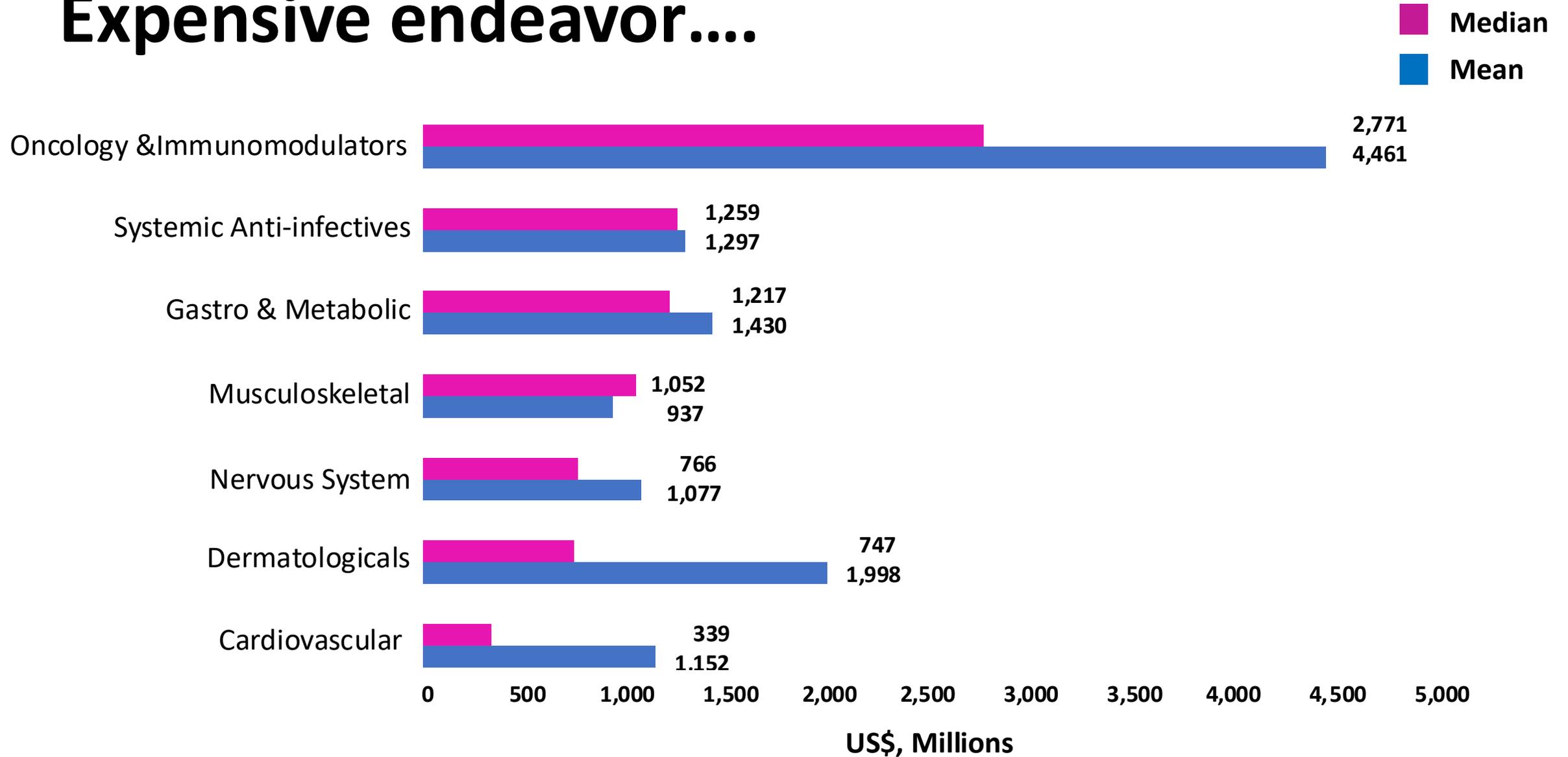


Drug Development Funding Strategies



Suzanne Tomlinson-Mathis, PhD, MBA
Director: Research Programs and Strategic Initiatives, GCC

Expensive endeavor....



Expensive endeavor...even at early stages



Expensive endeavor...even at early stages

Target→Hit	Hit→Lead	Lead Optimization	Preclinical	Phase 1	Phase 2	Phase 3	Submission→Launch
80%/24.3	75%/19.4	85%/14.6	69%/12.4	54%/8.6	34%/4.6	70%/1.6	91%/1.1
Probability of success/works in progress needed for one launch							
24/94	49/166	146/414	62/150	128/273	185/319	235/314	44/48
Cost per launch non-capitalized/capitalized (US\$ in Millions)							
1	1.5	2	2	1.5	2.5	2.5	1.5
Time (yrs)							

**Total
\$873/
1,778**

Which way do I go???



Funding within academia

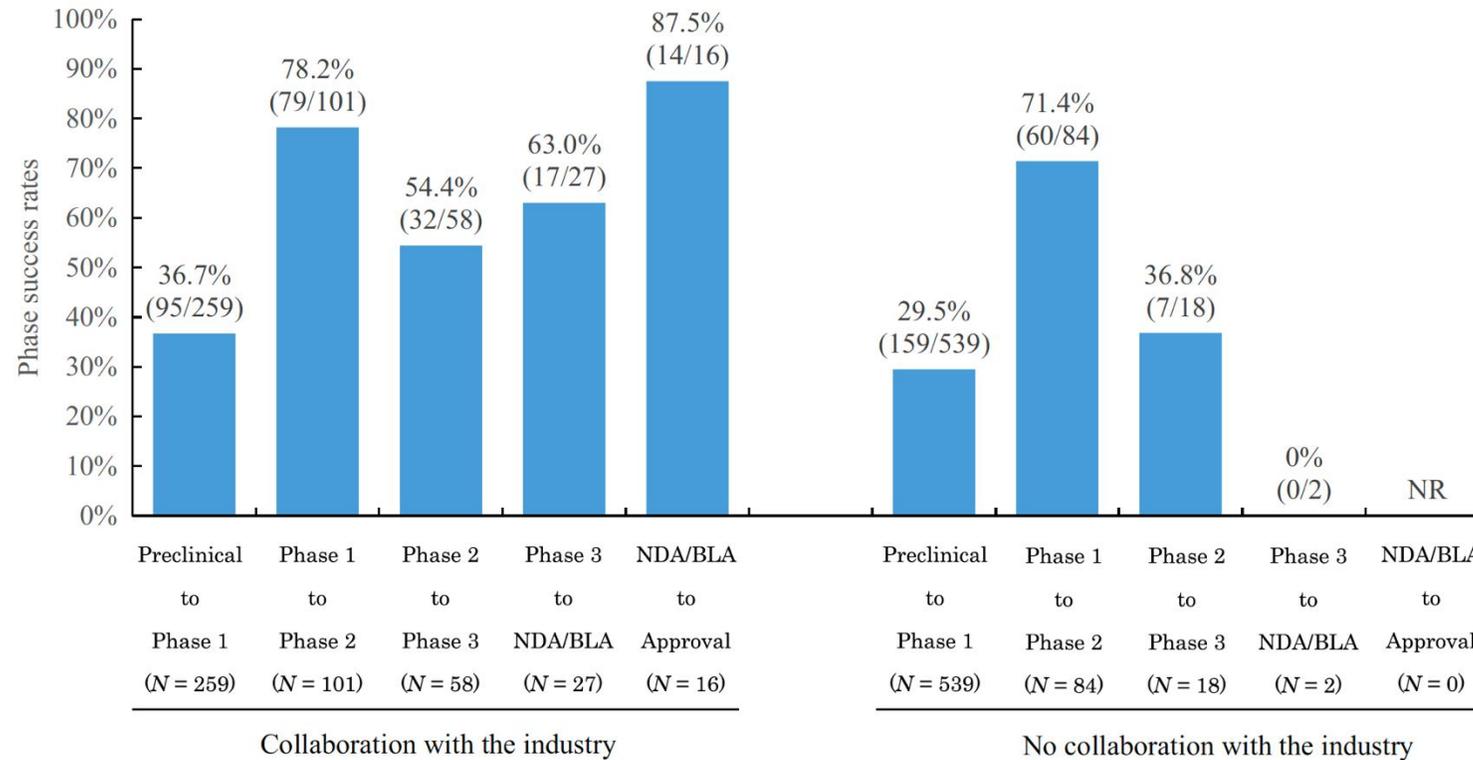
- Federal Funding
 - NIH
 - NSF
 - DARPA
 - DOD
 - MTEC
 - CDMRP
- State funding
 - CPRIT
 - CIRM
- Institutional
- Philanthropy
- Industry partnerships/collaborations

Often earlier stages

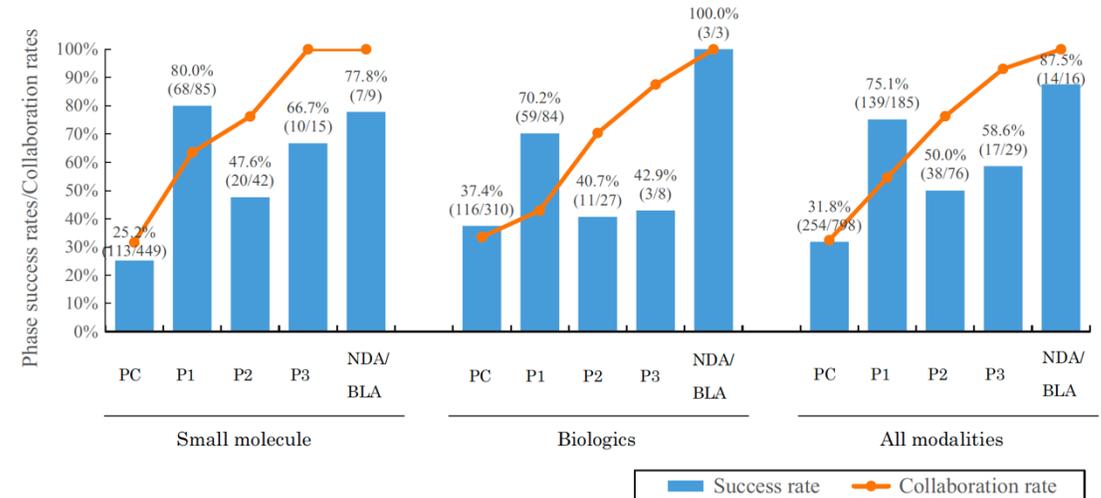
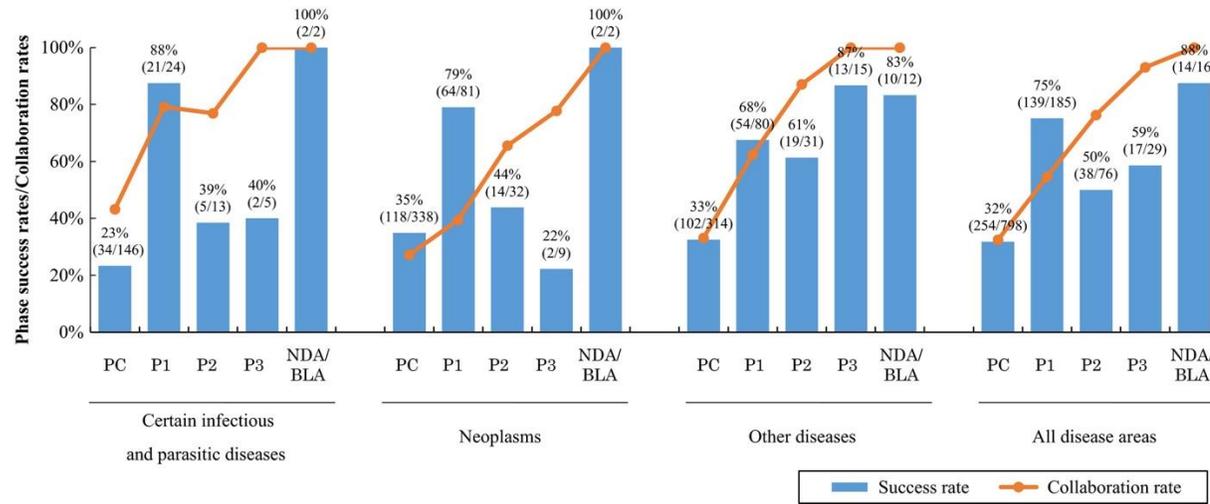


<https://www.addconsortium.org/>

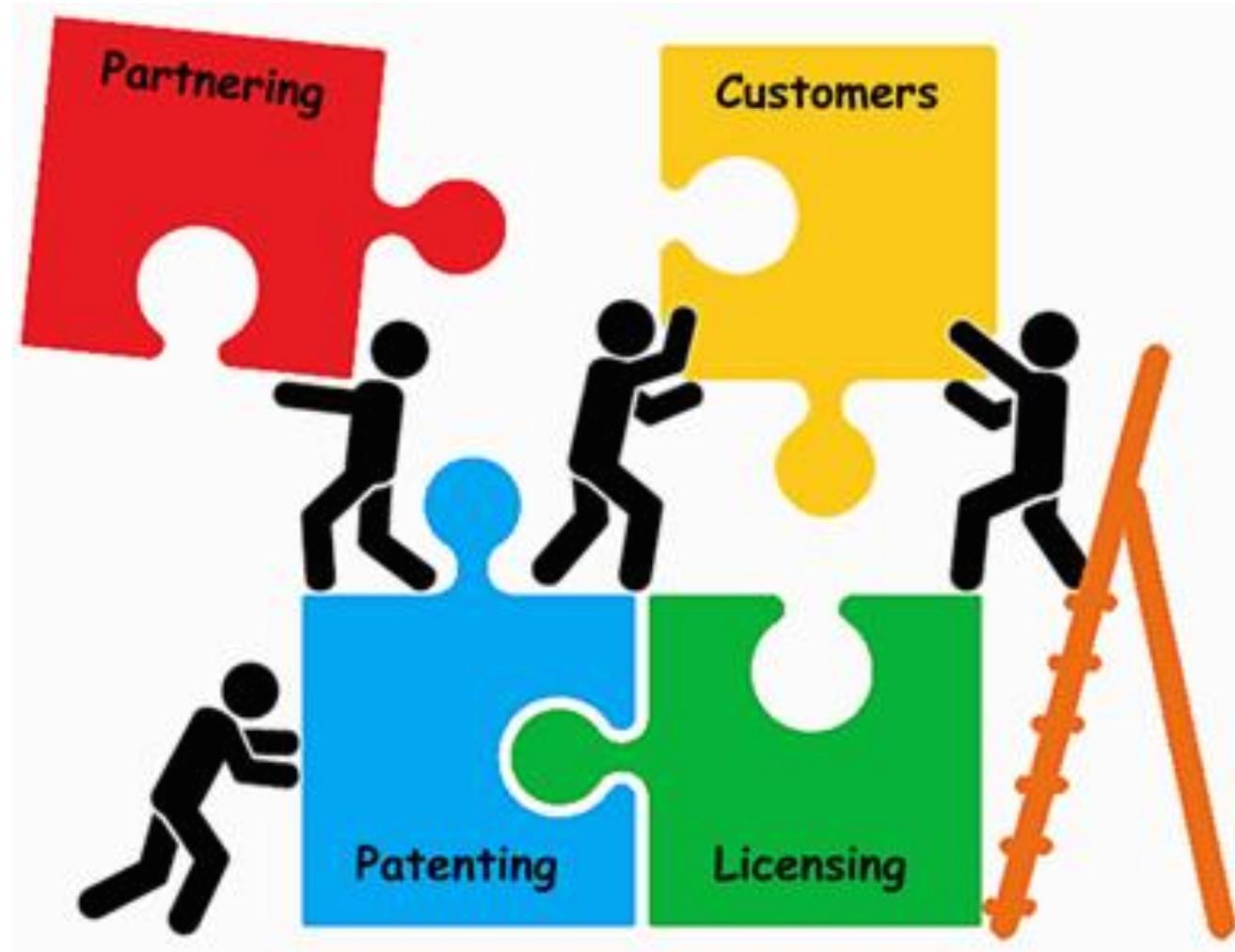
Academic-Industry partnerships/collaborations



Academic-Industry partnerships/collaborations



Working with your Tech Transfer Office



WHY?



Expensive endeavor...



Dilutive

Non-Dilutive

What is non-dilutive funding?

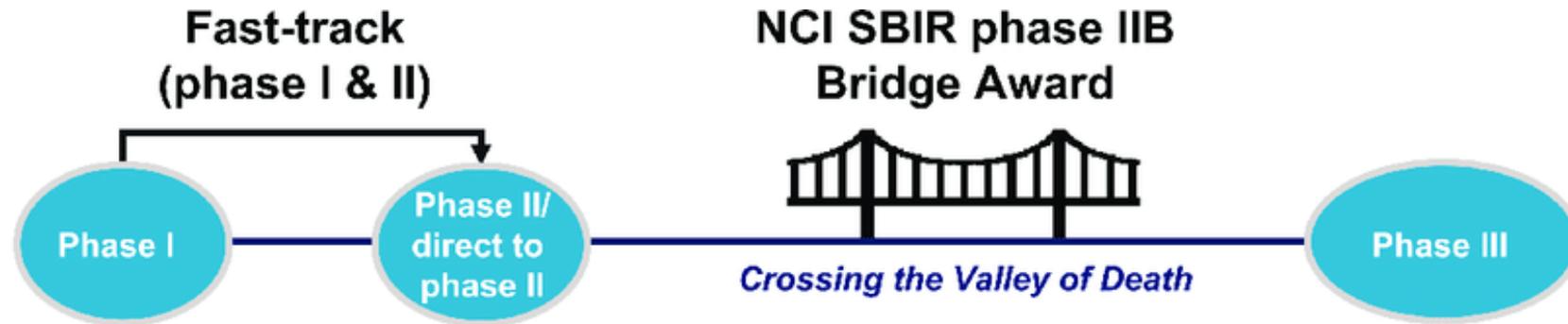
- Source of funding that does **not** require exchange of equity i.e. ownership is retained
 - Federal Funding → Grants
 - CPRIT
 - Debt
 - Awards

Non-dilutive funding?

- Source of funding that does not require exchange of equity i.e. ownership is retained
 - Federal Funding → Grants
 - CPRIT
 - Debt
 - Awards



Non-dilutive funding



- Proof-of-concept
- Up to \$400K over 6 to 12 months

- Research & development
- Commercialization plan required
- Up to \$2M over 2 years

- Technology validation & clinical translation
- Follow-on funding for SBIR phase II awardees from any federal agencies
- Expectation that applicants will secure substantial 3rd party investor funds
- **\$4 M over 3 years**

- Commercialization stage
- Use of non-SBIR/STTR funds

	Standard award	Hard cap	Waiver cap (IC specific)
Phase I	\$150,000	\$252,131	NCI: \$400,000
Phase II	\$1.0M	~\$1.68M	NCI: \$2.0M

Gulf Coast Consortia

The logo for REACH (Research Evaluation and Commercialization Hub) features a stylized graphic of two overlapping, curved bands in shades of teal and light blue, positioned to the left of the word "REACH" in a bold, teal, sans-serif font.

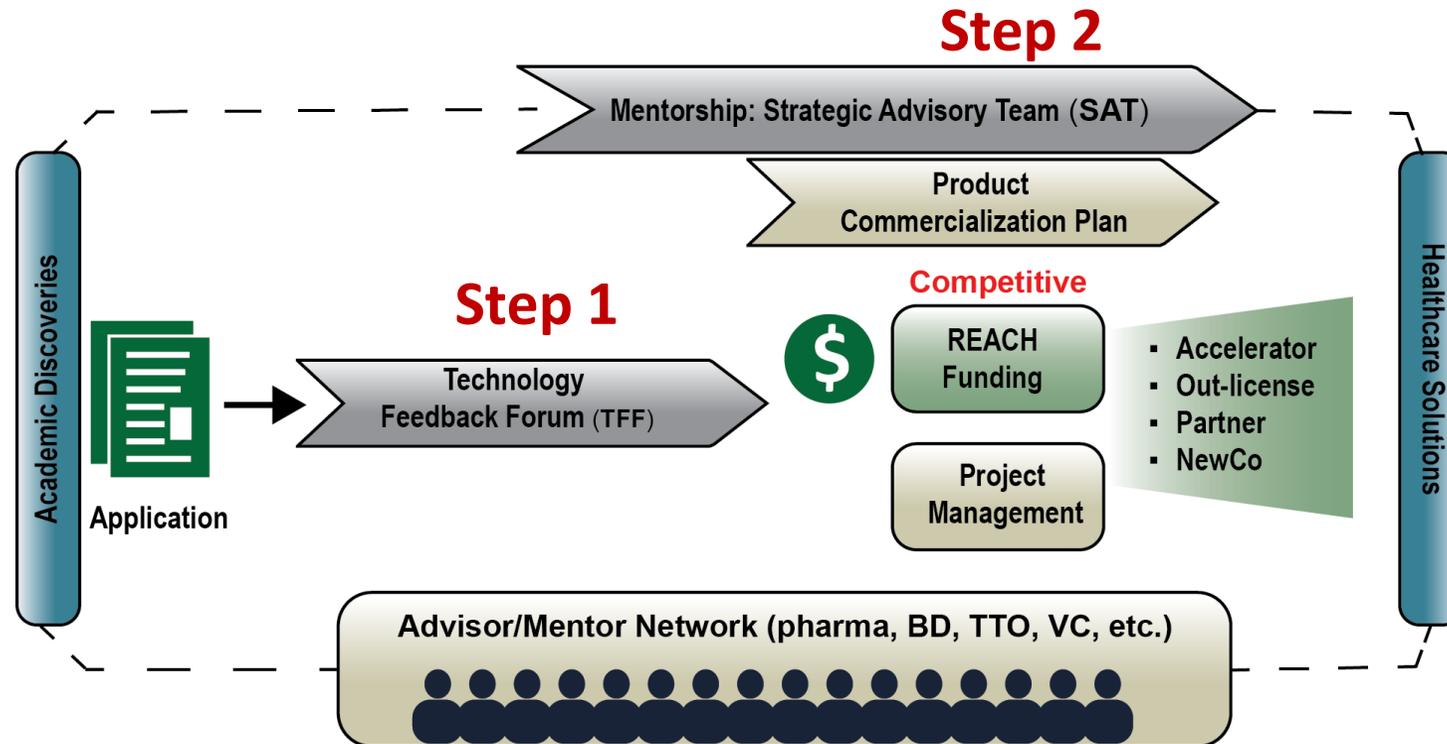
Research Evaluation and Commercialization Hub

- Collaboration with Tech Transfer Offices
- Strategic team development
- Seed funding for strategic milestones
- Vetted development resources
- SBIR/STTR support



Gulf Coast Consortia REACH

Research Evaluation and Commercialization Hub



Gulf Coast Consortia REACH

Research Evaluation and Commercialization Hub

- ***Open to ALL institutions***
- Strategic team development
- Seed funding for strategic milestones
- Vetted development resources
- SBIR/STTR support
- Rolling applications reviewed 3X/year; cutoffs 1/31, 5/31, 9/31
- ***Open to all entrepreneurs (students and postdocs included)***

**1st Cohort Application
Deadline January 31**



Lacey Tezino
REACH Program
Manager



Dillon Fritz
REACH
Entrepreneur-In-Residence



gccreach.org

Non-dilutive funding

- Source of funding that does **not** require exchange of equity i.e. ownership is retained
 - Federal Funding → Grants
 - CPRIT
 - Debt
 - Awards



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Non-dilutive funding



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

2007 – Texas voted in favor of \$3B in general obligation bonds to fund cancer research in Texas through the creation of the Cancer Prevention Research Institute of Texas

2019 – Texas voted to approve a constitutional amendment authorizing an additional \$3B in general obligation bonds to CPRIT

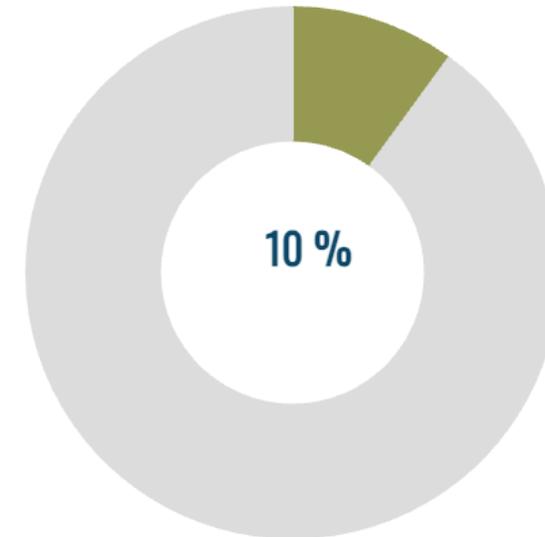
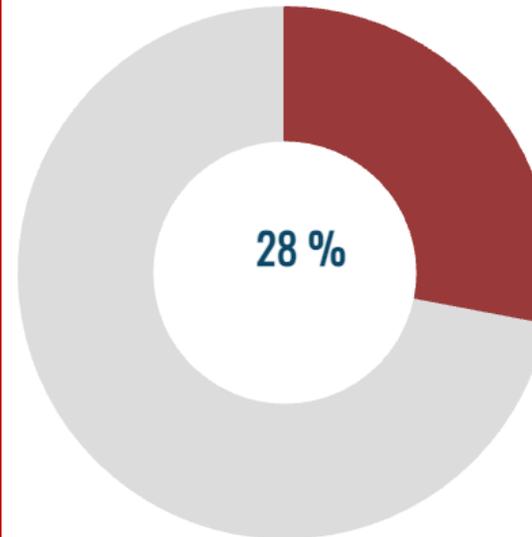
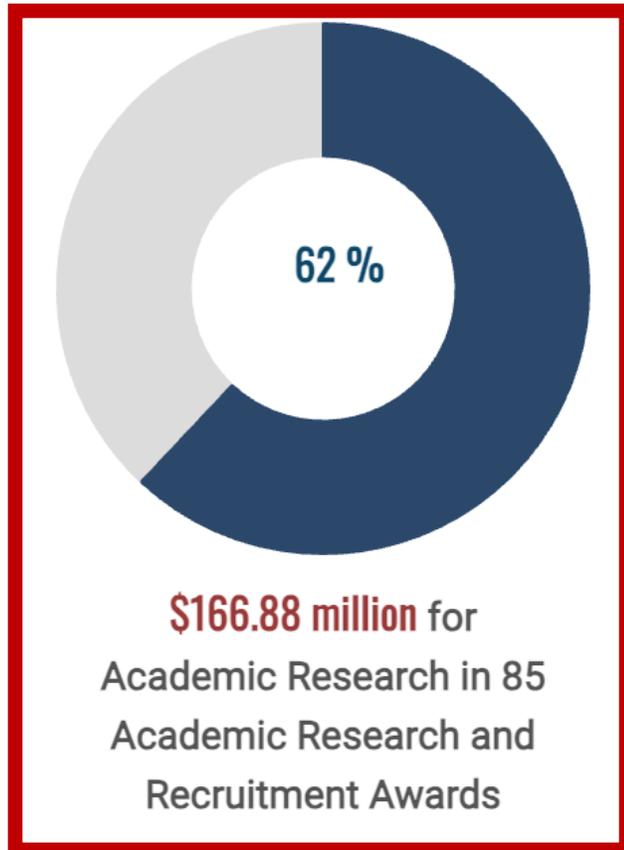
\$6B

Non-dilutive funding



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

\$269.04 million in Grant Funds Awarded and 109 Grants Approved in FY 2023



29 Organizations Receiving Grants

<https://2023annualreport.cprit.texas.gov/highlights/#milestones>

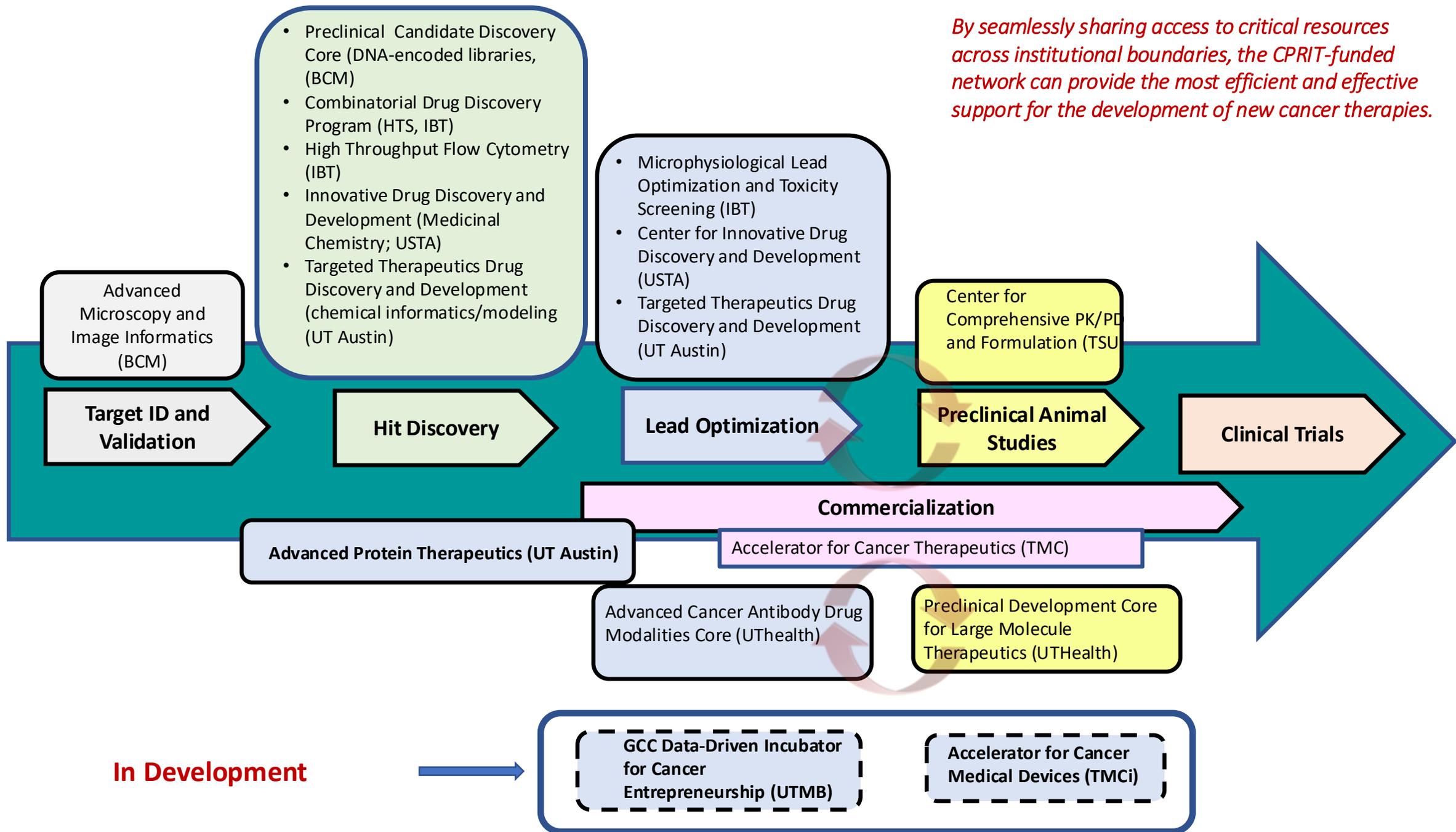


CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Cancer Therapeutics Training Program (CTTP)



By seamlessly sharing access to critical resources across institutional boundaries, the CPRIT-funded network can provide the most efficient and effective support for the development of new cancer therapies.

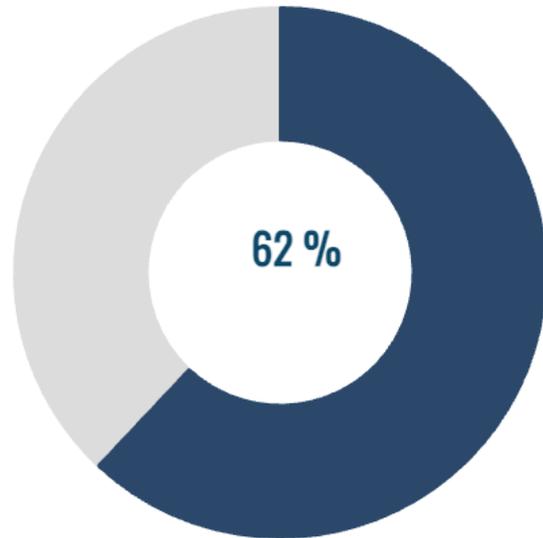


Non-dilutive funding

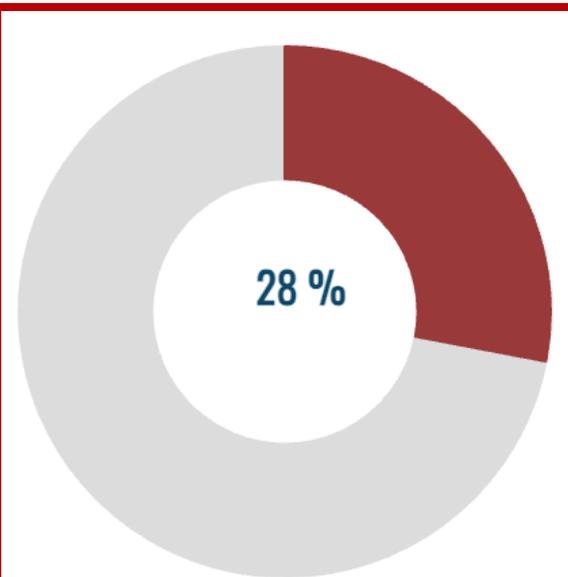


CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

\$269.04 million in Grant Funds Awarded and 109 Grants Approved in FY 2023

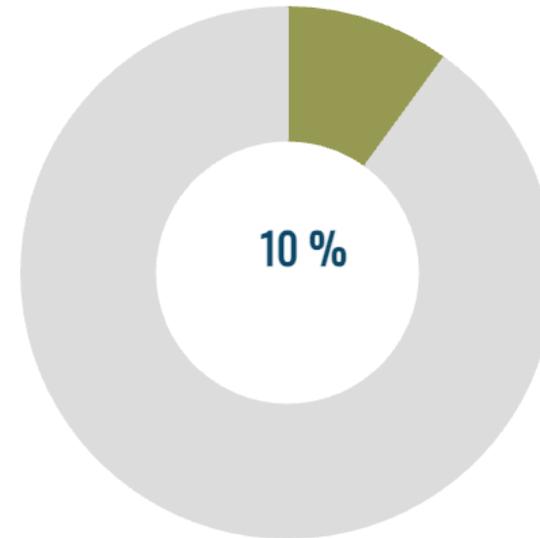


\$166.88 million for
Academic Research in 85
Academic Research and
Recruitment Awards



\$75.2 million for Product
Development Research in
7 awards

29 Organizations Receiving Grants



\$26.9 million for
Prevention in 17 Awards

<https://2023annualreport.cprit.texas.gov/highlights/#milestones>

Non-dilutive funding



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

- Texas Therapeutics, Diagnostic and devices, New Technologies Company RFA
 - No maximum – up to 3 years
 - More advanced projects typically either in P1 or within 1 year of IND/IDE
 - Can fund preclinical safety and efficacy studies, CMC, GLP safety to support INDs, P1 and P2
 - Comprehensive development plan (e.g. regulatory, CTs, commercialization)
 - Detailed business plan
- **Primary Review Criteria**
 - Significance and Impact
 - Product validation/POC
 - Safety
 - Preclinical strength and development to date
 - ***Detailed business plan***
 - ***Development plan***
 - ***Competitive landscape***
 - ***Intellectual property***
 - ***Business/commercial aspects***
 - ***Management and staffing***
 - ***Production/manufacturing plan***
 - ***Clinical/regulatory plan overview***

Non-dilutive funding



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

- SEED Award for Product Development Research
 - Up to \$3M over 3 years
 - May be earlier stage
 - Can fund target validation, lead optimization, preliminary efficacy and safety confirmation, demonstration of manufacturability
 - Traunched funding tied to milestone achievement
 - Detailed business plan

Requirements

- Must commit to be Texas based
- 2:1 match; company must raise \$1 for every \$2 provided by CPRIT (for 1st CPRIT PD award)

Non-dilutive funding



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

SEED Award for Product Development Research

- Identified a novel therapeutic, diagnostic technology, or clinical tool and shown a biological effect
- Replicated/verified the research in a second model and in a second lab
- Conducted preliminary safety and toxicology testing (in the case of therapeutic agents)
- Shown the product can be manufactured at small scale or as a prototype
- Assessed the business opportunity and organized a business plan that begins to address key issues (clinical utility, target market, financial plan, IP strategy, technical challenges, etc) and lays out a preliminary development plan (formulation, toxicology, scale up, IND-enabling studies, phase 1 clinical trials, regulatory pathway, etc).
- Established key preclinical development milestones through IND submission
- Initiated a patent application
- Established a company

<https://www.cprit.state.tx.us/media/2612/rfa-c-222-seed.pdf>

What is dilutive funding?

- Source of funding that **does** require exchange of equity i.e. ownership in the business
 - Angel investors
 - Venture Studios
 - Venture Capital
 - Corporate venture



Venture Capital vs Corporate Venture Capital

CVC

VC

Structure

Investment arm owned by a corporation

Limited partners (LP) provide VC money to invest in startups

Benefit

Industry know-how, market knowledge, reputation, customer base, network

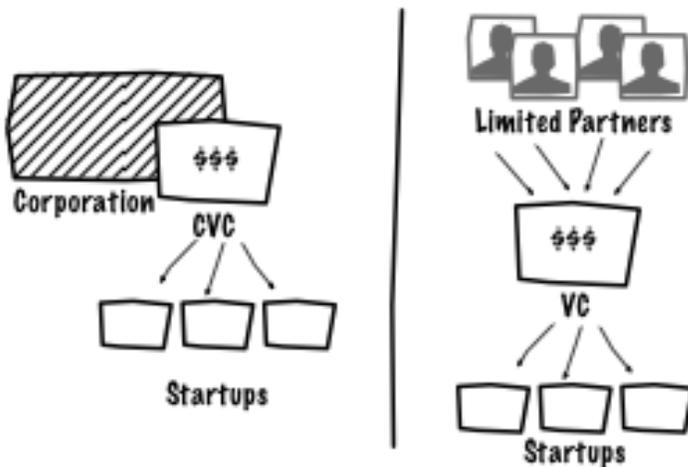
Money, network, scaling expertise

Exit goals

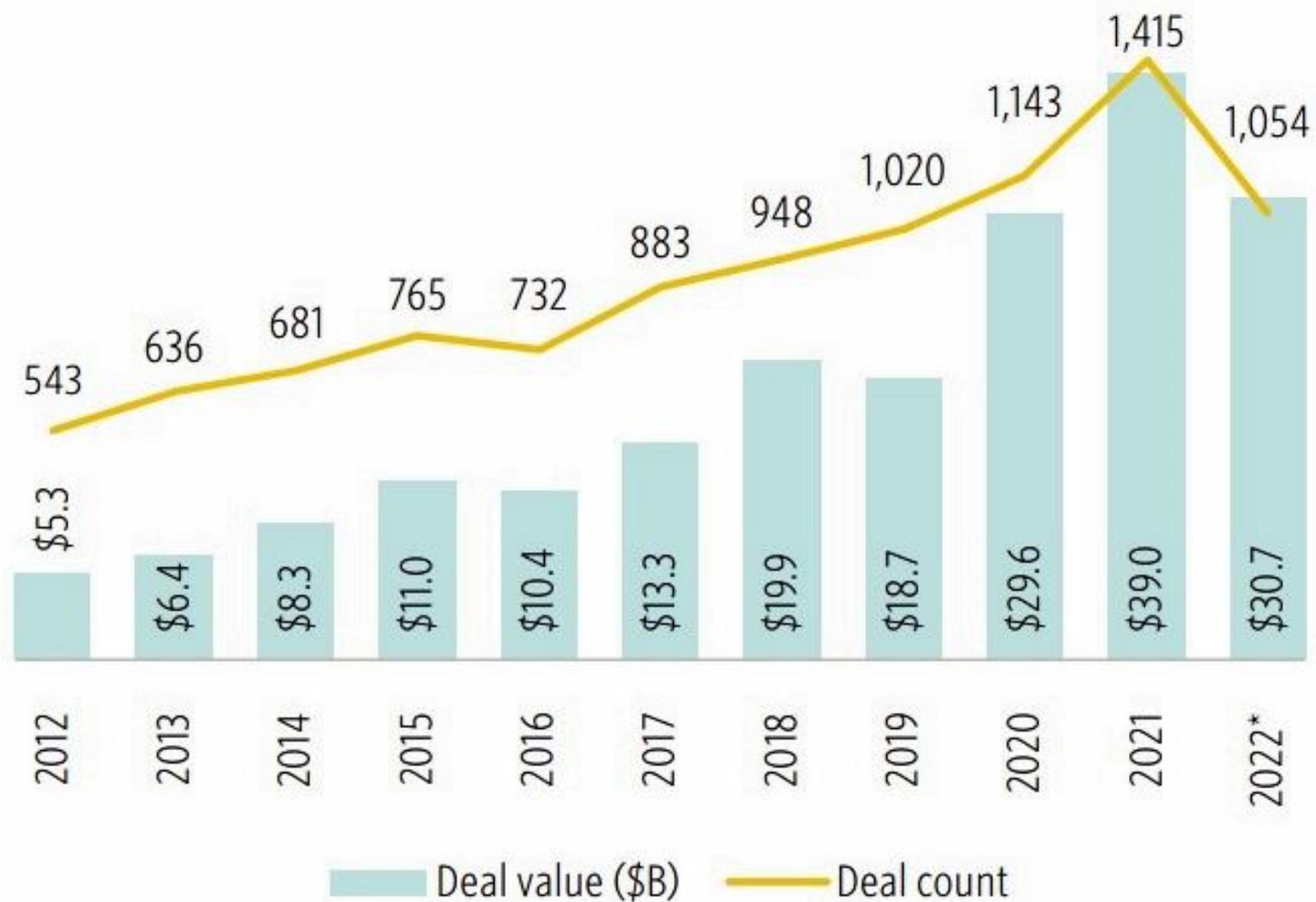
Less focus on exits but rather on strategic synergies and longer term partnerships

Typically push for exits like IPO or buyout from another fund or company

Corporate Venturing vs. Venture Capital



US biotech & pharma VC deal activity



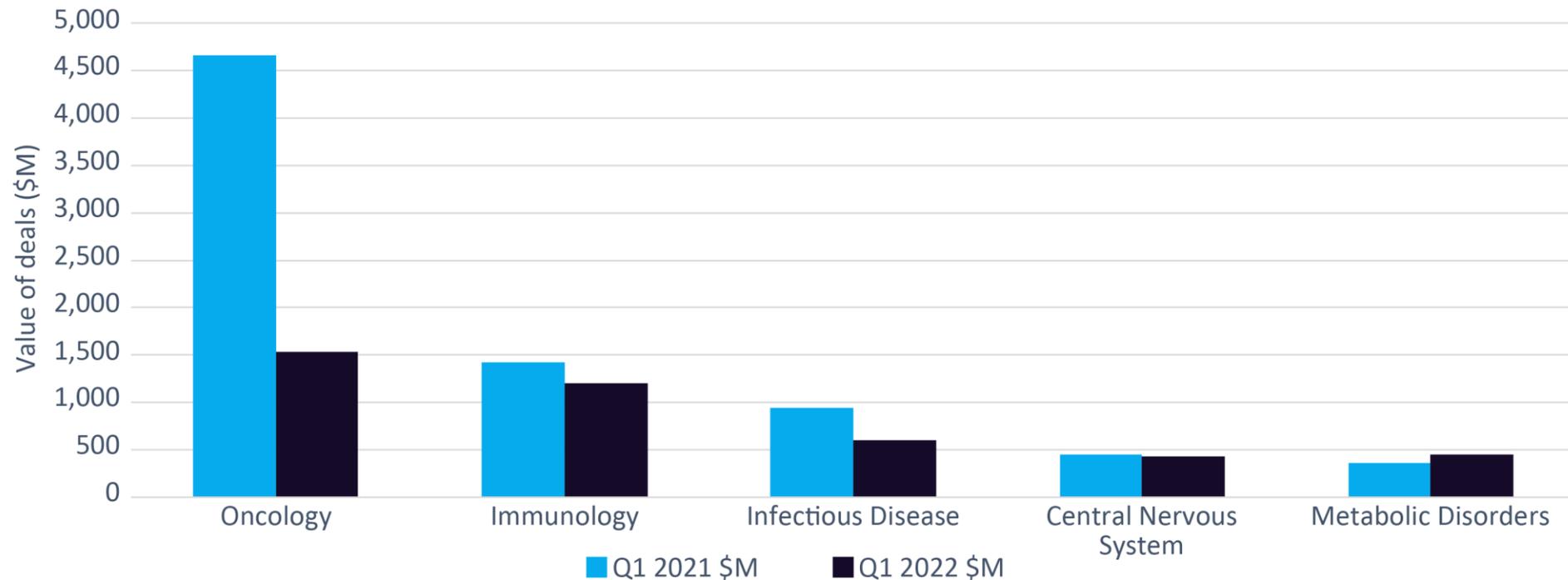
PitchBook-NVCA Venture Monitor

*As of December 31, 2022

What is dilutive funding?



Venture Financing for US-Headquartered Biopharmaceutical Companies for Top Five Therapy Areas



Source: GlobalData, Pharma Intelligence Center



<https://www.globaldata.com/media/pharma/venture-financing-deal-value-us-headquartered-biotechs-decreased-46-q1-2022-compared-q1-2021-finds-globaldata/>

Funding Careers Panel

COMING UP

Shahila Christi, Portal Innovations



Emily Reiser, TMC Ventures



Michael Heffernan, Fannin Innovation Studio

