Drug Development Funding Strategies

Suzanne Tomlinson
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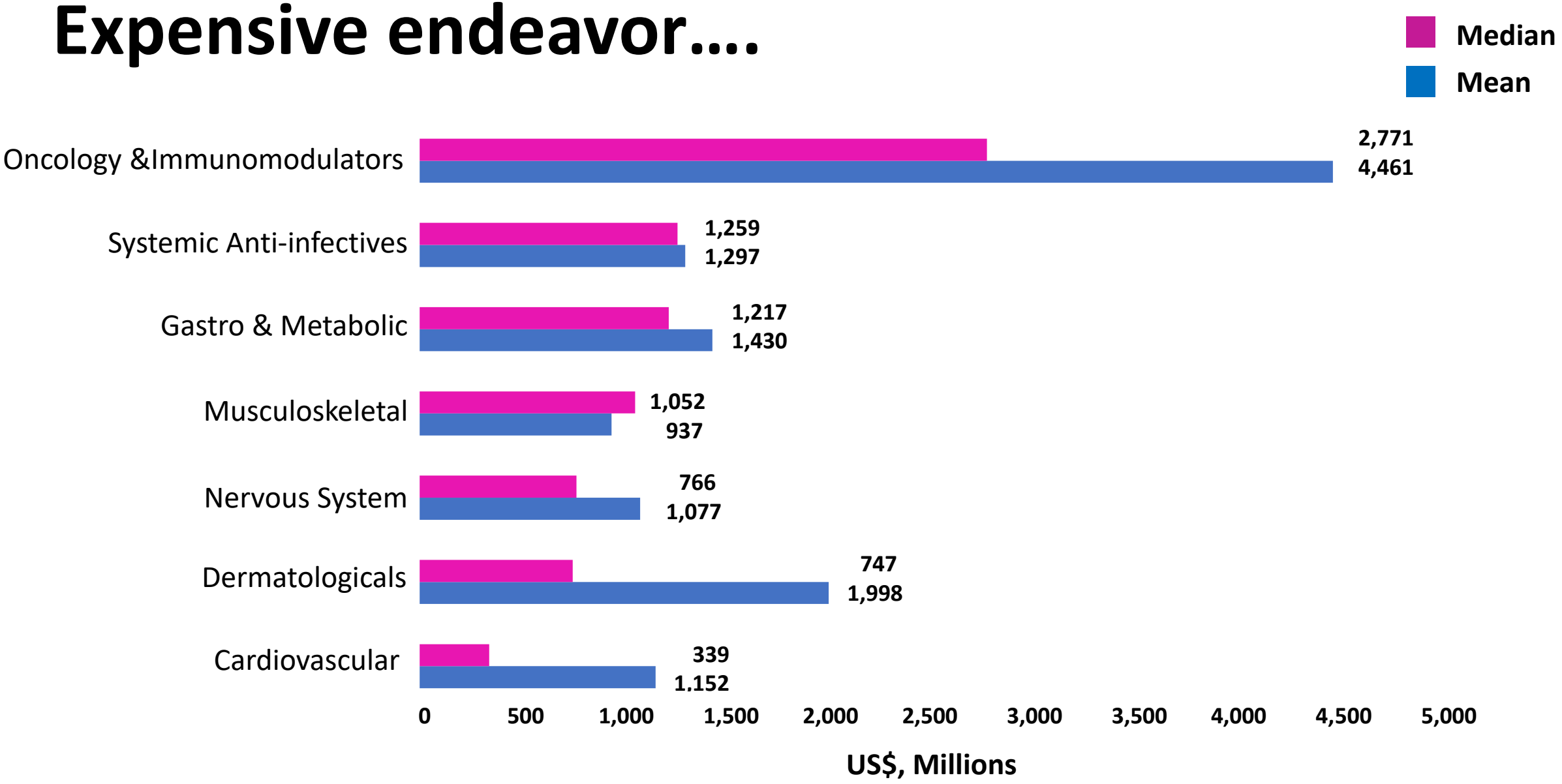
Gulf Coast Consortia
QUANTITATIVE BIOMEDICAL SCIENCES

Expensive endeavor….



Data from: *Wouters, et.al. Estimated Research and Development Investment Needed to Bring a New Medicine to Market 2009-2018, JAMA 2020; 323 (9) 844-853*

Expensive endeavor….even at early stages

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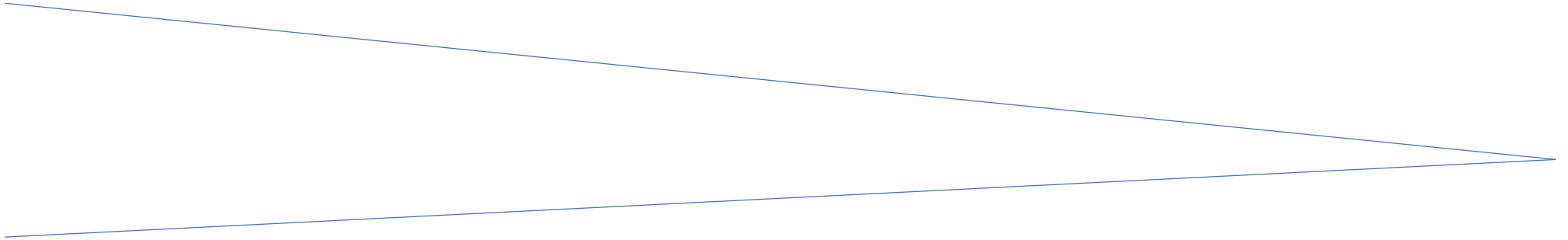


Target→Hit	Hit→Lead	Lead Optimization	Preclinical	Phase 1	Phase 2	Phase 3	Submission→Launch
24/ 94	49/ 166	146/ 414	62/ 150	128/ 273	185/ 319	235/ 314	44/ 48
Cost per launch non-capitalized/capitalized (US$ in Millions)							
1	1.5	2	2	1.5	2.5	2.5	1.5
Time (yrs)							

Total $873/ 1,778

Data from: *Paul et.al. How to Improve R&D Productivity: the Pharmaceutical Industry's Grand Challenge, Nat Rev Drug Discov. 2010; 9 (3) 203-214*

Which way do I go???

Funding within academia

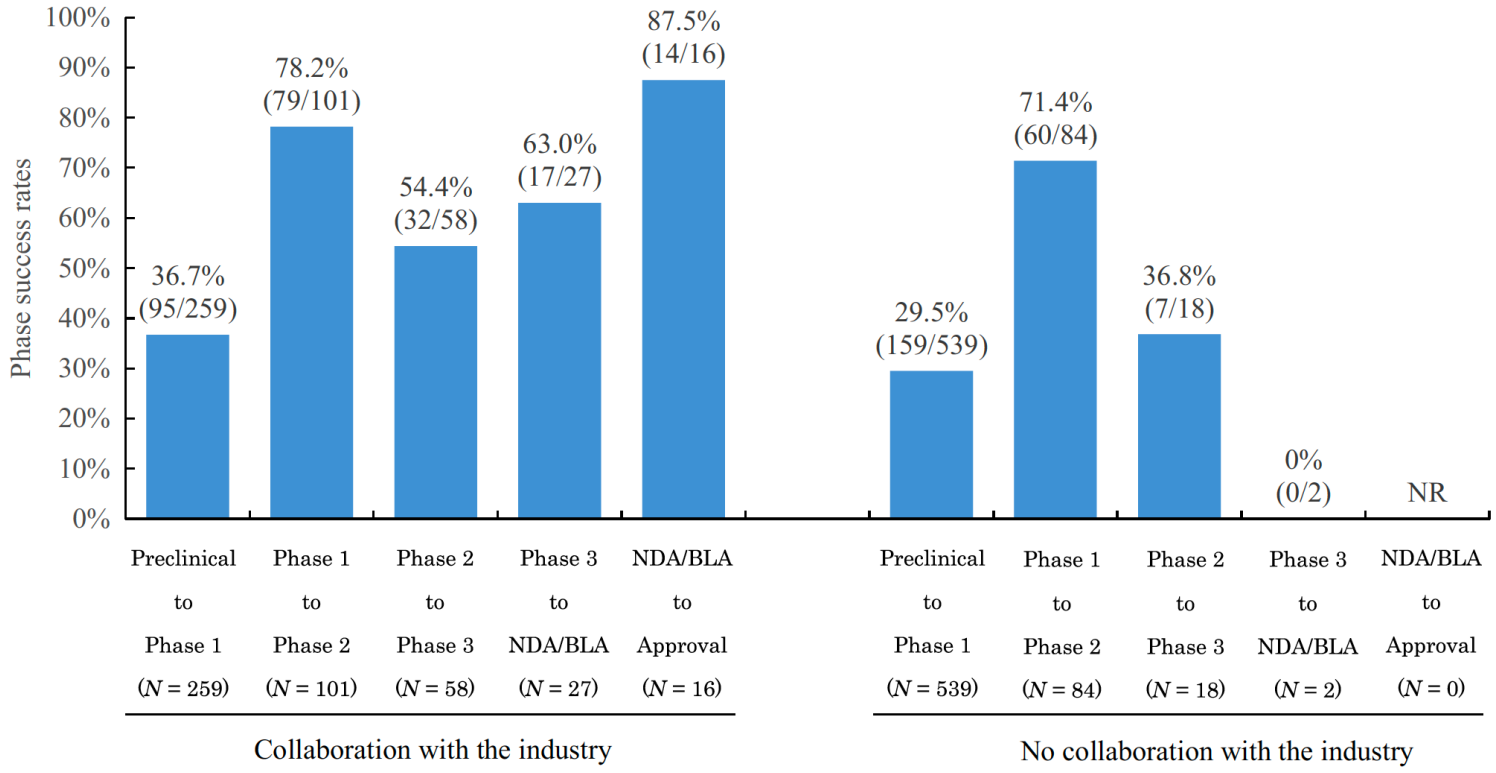
- Federal Funding
  - NIH
  - NSF
  - DARPA
  - DOD
    - MTEC
    - CDMRP
- State funding
  - CPRIT
  - CIRM
- Institutional
- Philanthropy
- Industry partnerships/collaborations

Often earlier stages

academic DRUGDISCOVERY consortium

https://www.addconsortium.org/

Academic-Industry partnerships/collaborations



Paul et.al., The Current Status of Drug Disc. and Dev. As Originated in US Academia: The Influence of Industrial and Academic Collaboration on Drug Disc. and Dev., Clin Transl Sci., 2018; 11, 597-606

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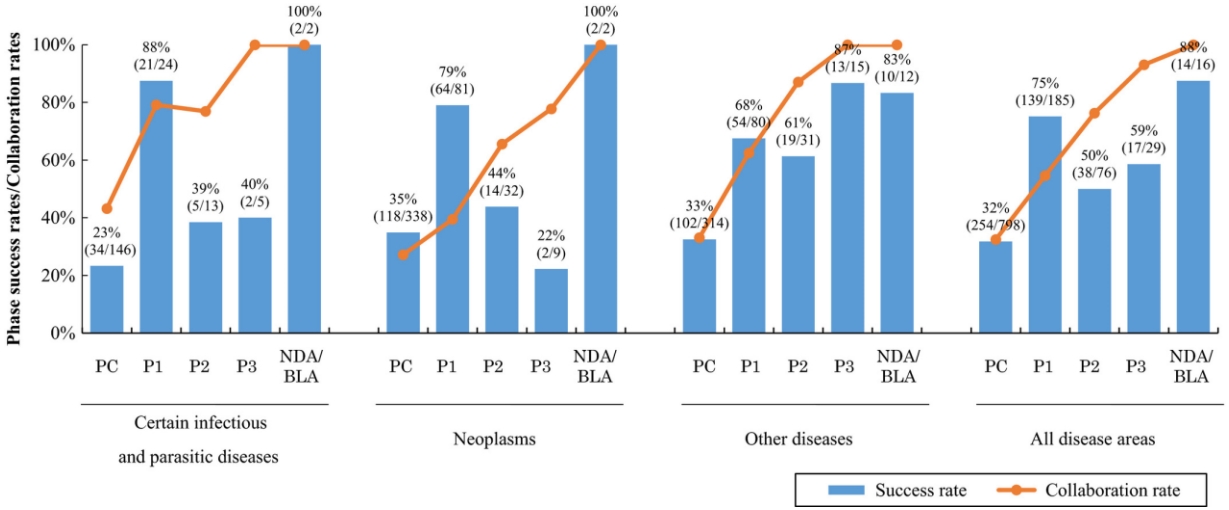

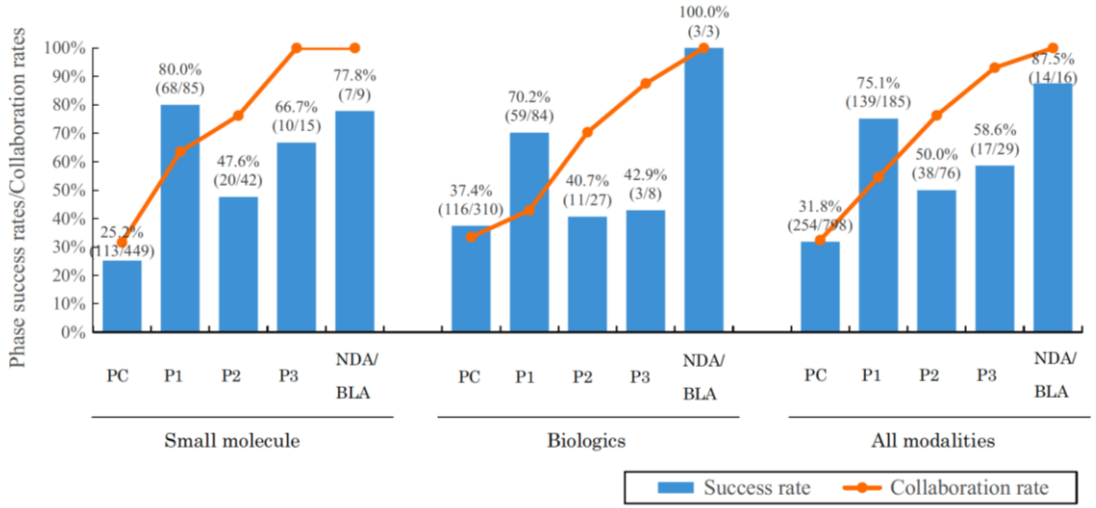

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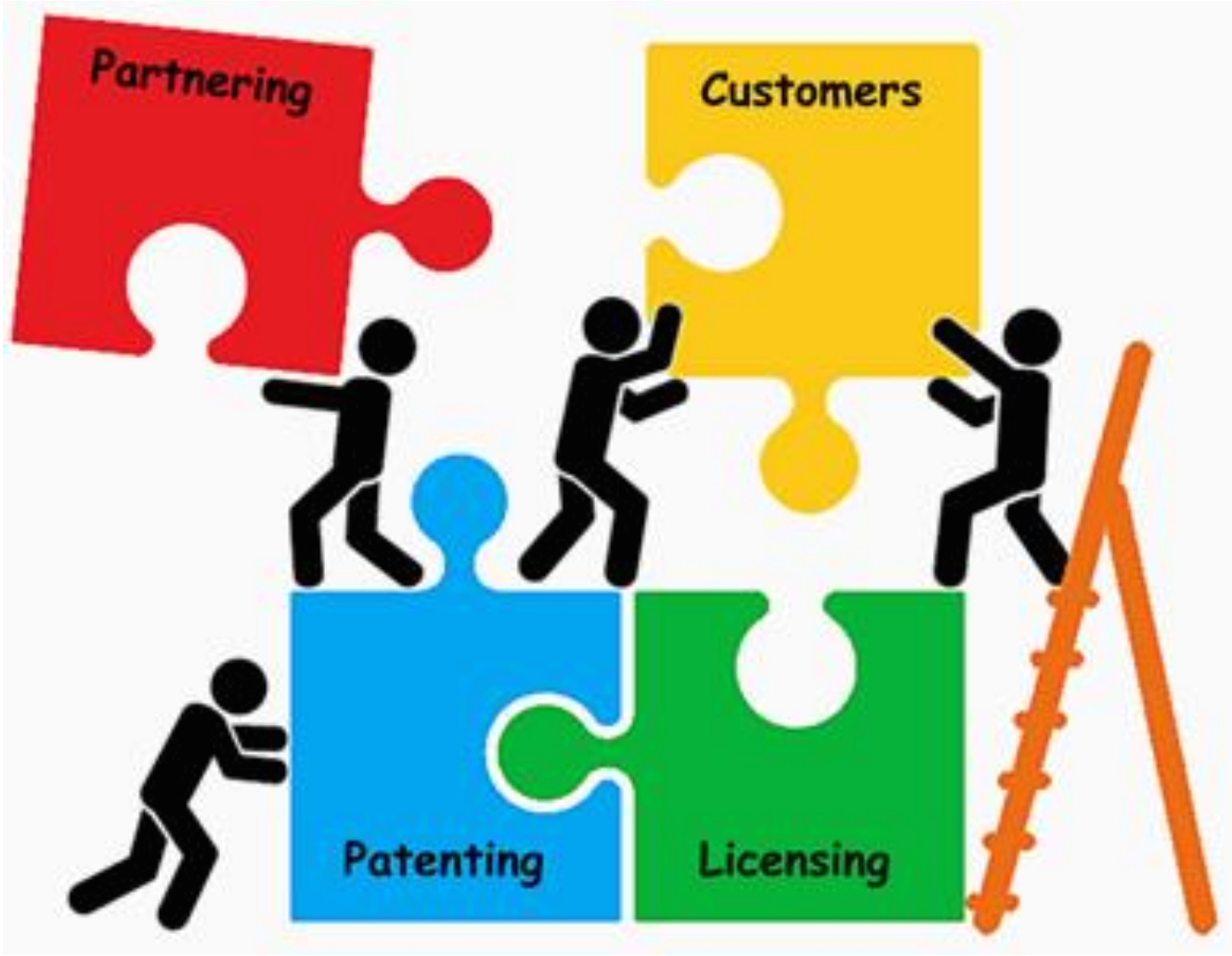
Working with your Tech Transfer Office




WHY?


Startup


OLD MacDONALD Had A STARTUP
C.I.E.I.O.

Expensive endeavor….

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?

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Non-dilutive funding

SBIR·STTR
America's Seed Fund™
POWERED BY SBA

- 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

Non-dilutive funding

	Small Business Innovation Research (SBIR)	Small Business Technology Transfer. (STTR)
PI employment	Small business	Small business or research institution
Subcontracted research	33% in Phase 1; 50% in Phase 2	Up to 60%
# participating agencies	11	5
Research institution	Not required	Required
IP allocation agreement	Not required	Required
Phase 1	6 months	12 months

Deadlines: April 5, September 5, and January 5 → Award ~ 6 months after deadline

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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

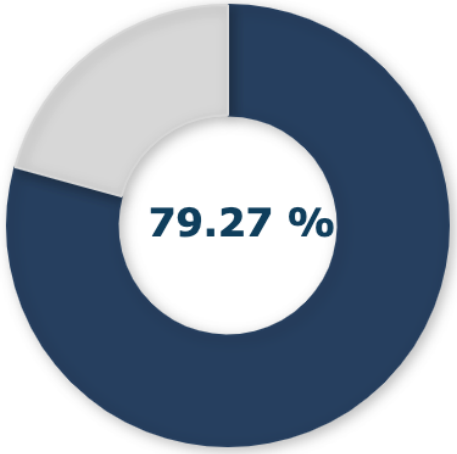
2019 – Texas voted to approve a constitutional amendment authorizing an additional $3B in general obligation bonds to CPRIT

$6B

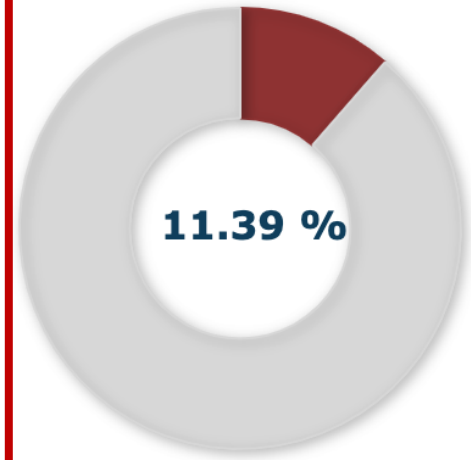
Non-dilutive funding

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

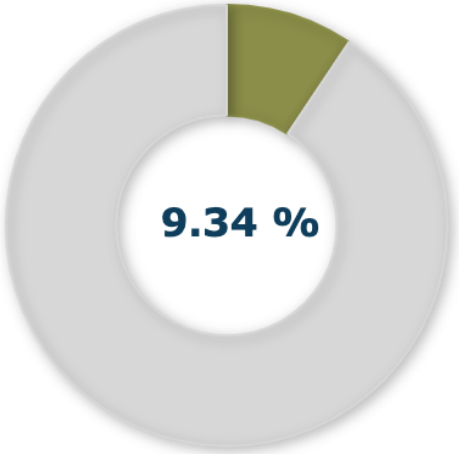
$241.9 million in Grant Funds Awarded and 107 Grants Approved in 2021



$191.7 million for Academic Research in **91** Academic Research and Recruitment Awards



$27.56 million for Product Development Research in **2** awards



$22.59 million for Prevention in **14** Awards

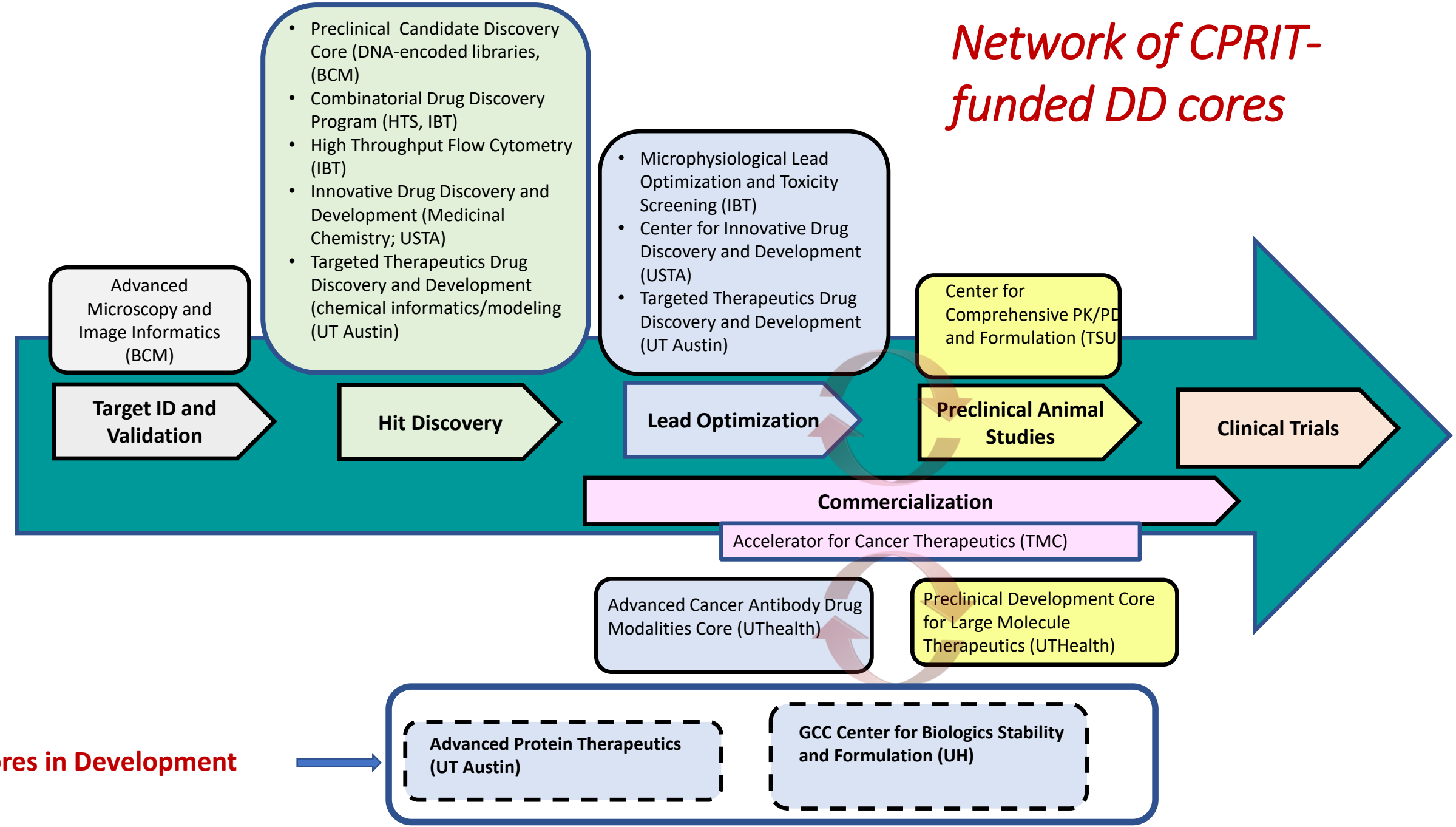
27 Organizations Receiving Grants

https://2021annualreport.cprit.texas.gov/highlights

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Cancer Therapeutics Training Program (CTTP)

Network of CPRIT-funded DD cores



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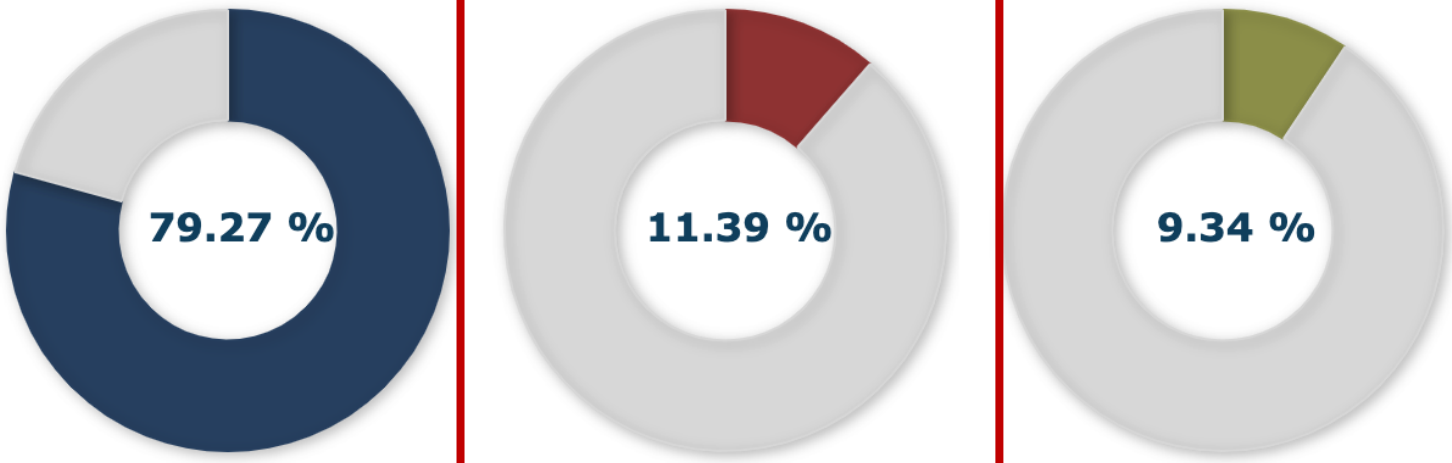

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Non-dilutive funding

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

- Texas Therapeutics Company RFA
  - Up to $20M over 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***

https://www.cprit.texas.gov/media/2616/rfa-c-222-txco.pdf

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
  - Tranched 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

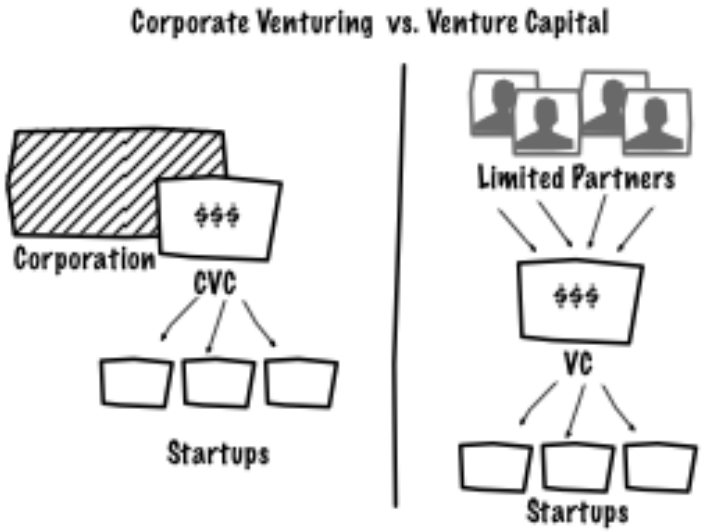
- Identified a novel therapeutic, diagnostic technology, or clinical tool and shown a biological effect
- Replicated/verified the research in a second model and in a second lab
- Conducted preliminary safety and toxicology testing (in the case of therapeutic agents)
- Shown the product can be manufactured 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?

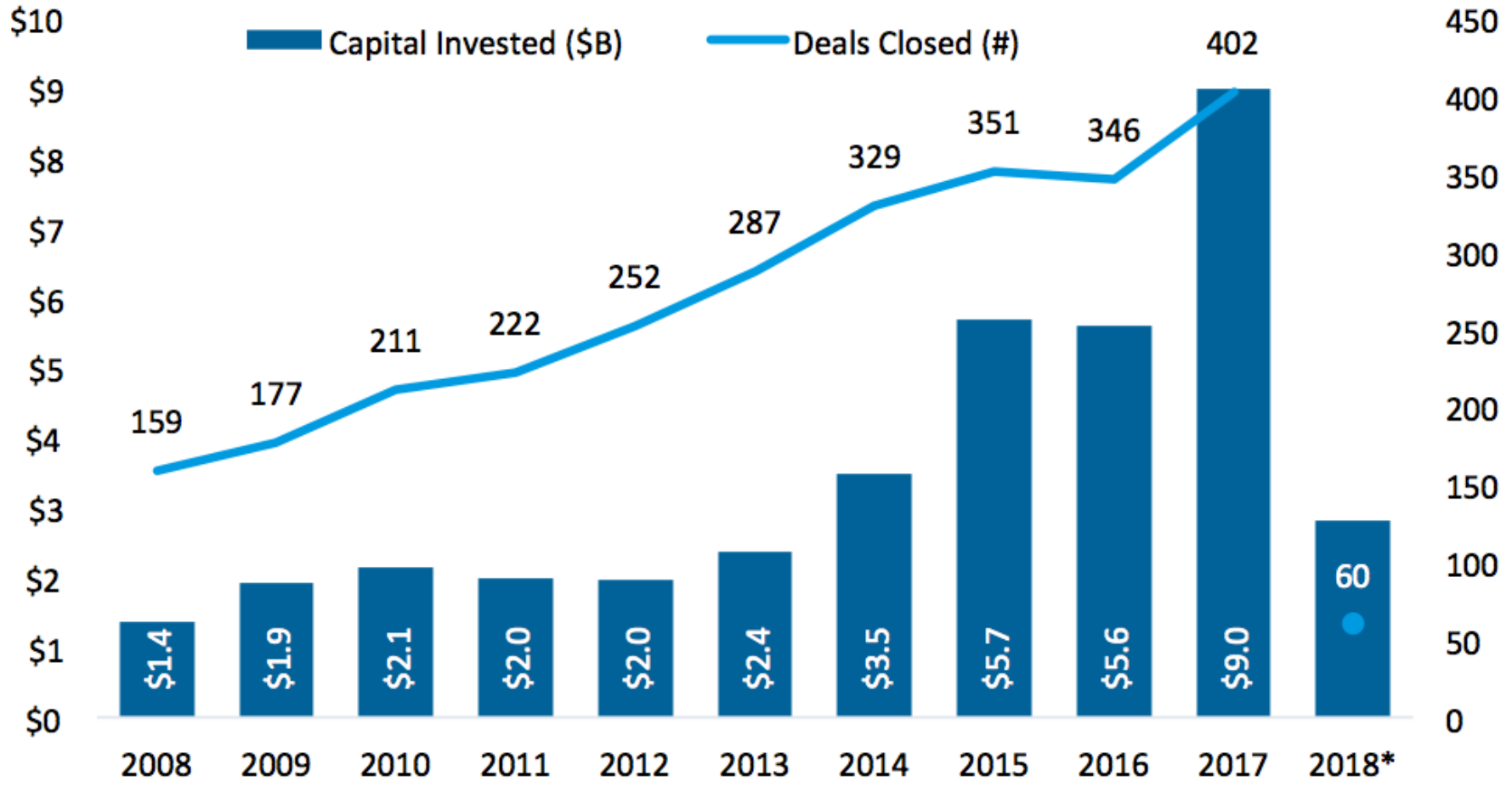
- Source of funding that ***does*** require exchange of equity i.e. ownership in the business
  - Angel investors
  - Venture Studios
  - Venture Capital
  - Corporate venture

Venture Capital vs Corporate Venture Capital



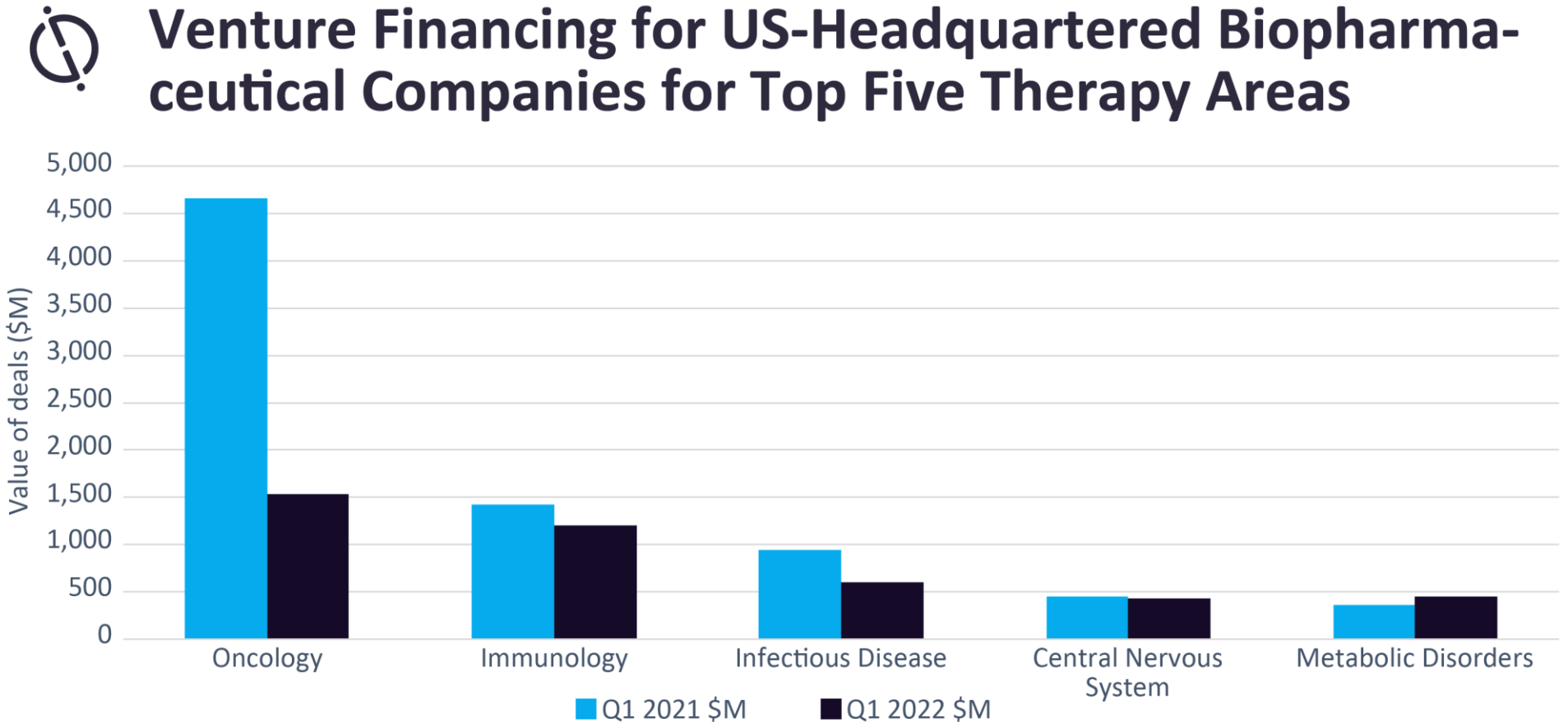
	CVC	VC
Structure	Investment arm owned by a corporation	Limited partners (LP) provide VC money to invest in startups
Benefit	Industry know-how, market knowledge, reputation, customer base, network	Money, network, scaling expertise
Exit goals	Less focus on exits but rather on strategic synergies and longer term partnerships	Typically push for exits like IPO or buyout from another fund or company

What is dilutive funding?



https://www.forbes.com/sites/matthewherper/2018/03/05/in-two-months-biotech-startups-raised-more-money-than-in-all-of-2013/?sh=4e3156957be7

What is dilutive funding?



Source: GlobalData, Pharma Intelligence Center

GlobalData.

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

Shahila Christi, Portal Innovations

Rima Chakrabarti, KDT Ventures

Stan Watowich, Ridgeline Therapeutics, UTMB

Michael Heffernan, Fannin Innovation Studio

Portal Innovations

KdT Ventures

Ridgeline Therapeutics

FANNIN
INNOVATION STUDIO