

DEC 3, 2021 | NCI TRP WEBINAR

# NCI SBIR Funding for Drug Development



**KORY HALLETT, PHD**  
LEAD PROGRAM DIRECTOR  
NCI SBIR DEVELOPMENT CENTER





# ABOUT SBIR & STTR

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# SBIR PROGRAMS

## 11 Federal Agencies



Department of Defense

Department of Health and Human Services

Department of Energy

National Science Foundation

National Aeronautics and Space Administration

Department of Agriculture

Department of Homeland Security

Department of Commerce

Department of Transportation

Department of Education

Environmental Protection Agency

# CONGRESSIONALLY MANDATED PROGRAM

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			Set Aside for FY20
<b>SBIR</b> SMALL BUSINESS INNOVATION RESEARCH	Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization <i>Federal agencies with an extramural R&amp;D budget &gt; \$100M</i>		<b>\$157M (3.2%)</b>
<b>STTR</b> SMALL BUSINESS TECHNOLOGY TRANSFER	Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization <i>Federal agencies with an extramural R&amp;D budget &gt; \$1B</i>		<b>\$22M (0.45%)</b>
Total			<b>\$1.18B for NIH \$179M for NCI</b>

# CRITICAL DIFFERENCES

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SBIR	STTR
<p><u>Permits</u> research institution partners (e.g., universities)</p>	<p><u>Requires</u> research institution partners (e.g., universities)</p>
<p>Small business may outsource ~33% of Phase I activities and 50% of Phase II activities</p>	<p>Minimum 40% of the work should be conducted by the small business (for profit), and minimum of 30% by a U.S. research institution (non-profit)</p>
<p>The PD/PI's primary employment (i.e., &gt;50%) MUST be with the SBC for the duration of the project period</p>	<p>PI primary employment not stipulated (min.10% effort to project)</p>

**The award is **ALWAYS** made to the small business concern.**

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# WHO ARE SBIR/STTR APPLICANTS?

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**Aruna Gambhir, MS, MBA**

CEO and Co-Founder, CellSight Technologies

“Investors want to see that a technology works. SBIR funding has been critical to our company to show that our technology works.”



“My laboratory was working in drug development and it takes a long time to license a technology. It was hard to push forward with only R01 funding and we had neat technology, worth pursuing.”



**Lori Hazlehurst, Ph.D.**

Professor, Pharmaceutical Sciences  
West Virginia University

President and Co-founder, Modulation Therapeutics

# ELIGIBILITY

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Applicant must be a Small Business Concern (SBC)



Organized for-profit U.S. business (based in the U.S. and work performed in the U.S.)



500 or fewer employees, including affiliates



> 50% U.S.- owned by individuals and independently operated

**OR**

> 50% owned & controlled by another (one) business concern that is > 50% owned & controlled by one or more individuals

**OR**

> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these (**SBIR ONLY**)

# WHY SEEK SBIR FUNDING?

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**Provides seed funding for innovative technology development //**

**Not a Loan**

No repayment is required  
Doesn't impact stock or shares in any way (i.e., non-dilutive.)



**Intellectual property rights retained by the small business //**

NIH does not request intellectual property for the SBIR- or STTR-funded technologies.



**Provides recognition, verification, and visibility //**

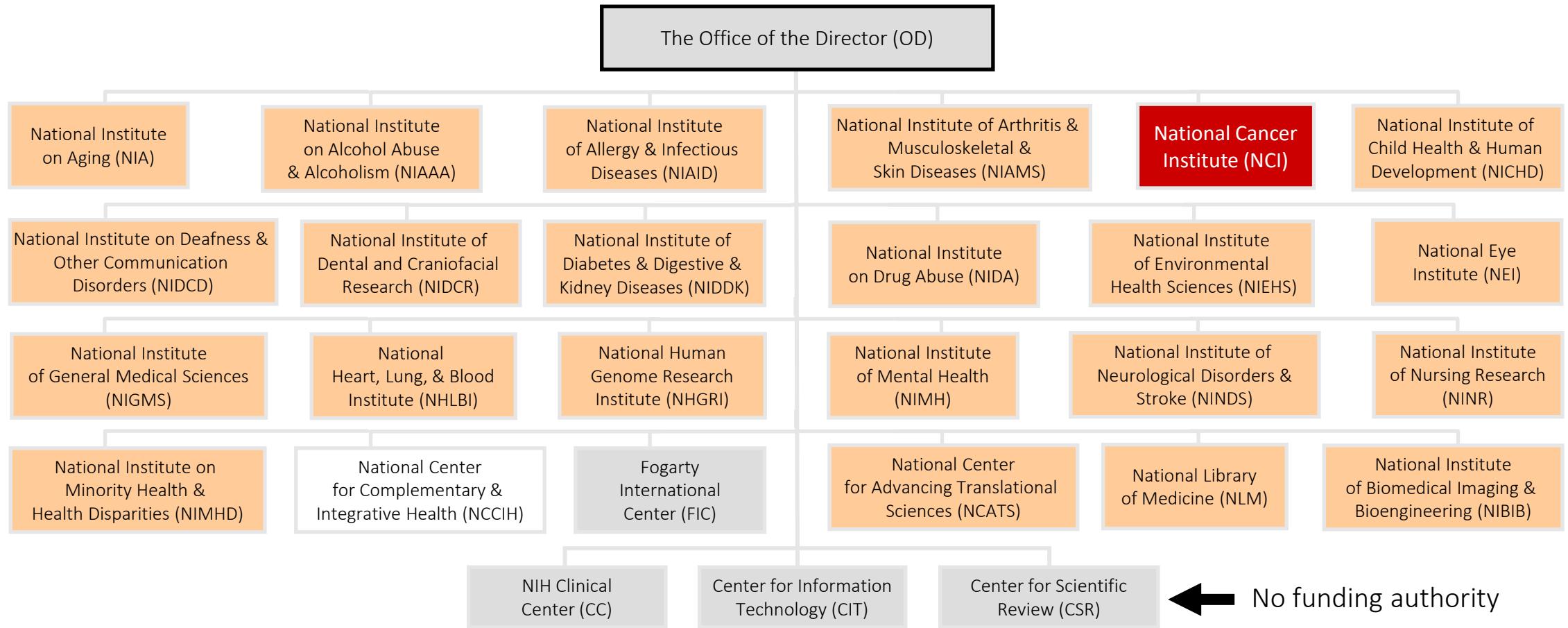
Every application is rigorously assessed by NIH Peer Review system.



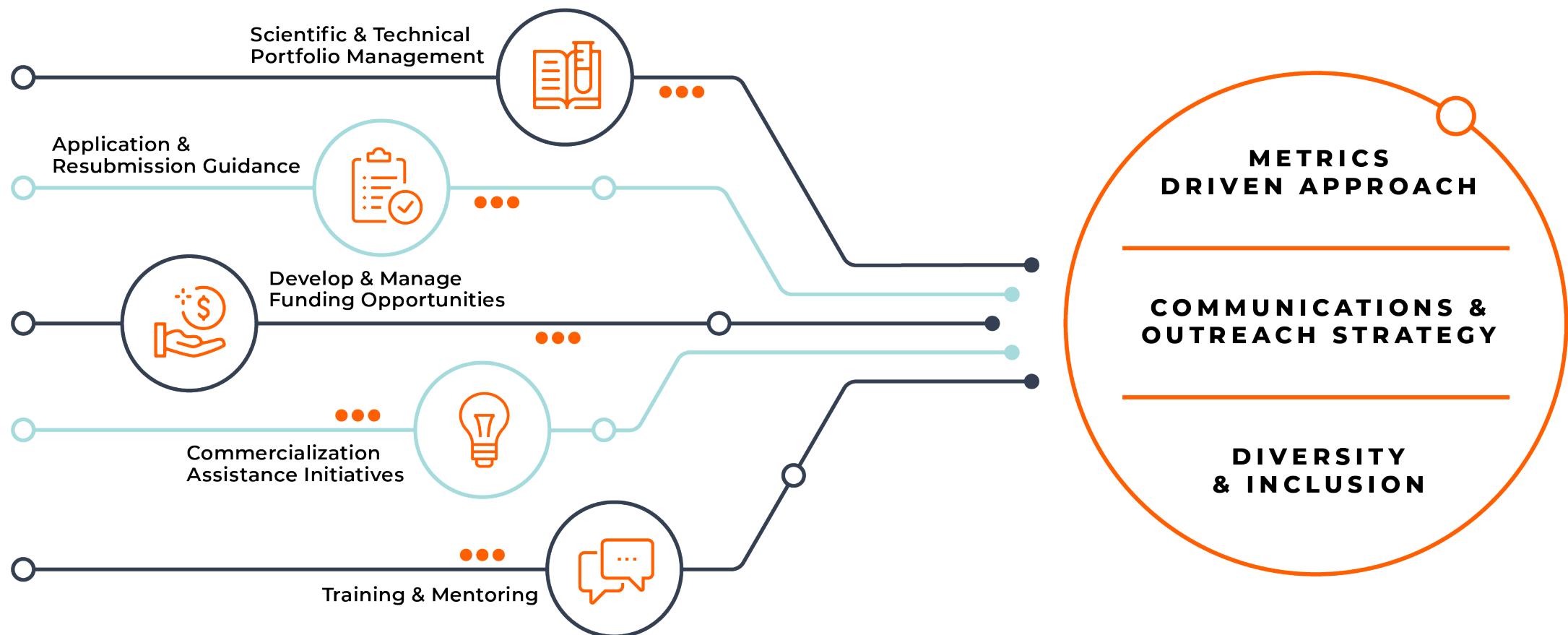
**Helps provide leverage in attracting additional funding or support //**

In addition to funding, we provide commercialization resources to help advance your project.

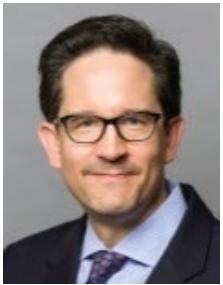
# 27 INSTITUTES & CENTERS AT THE NIH



# NCI SBIR DEVELOPMENT CENTER: CORE ACTIVITIES



# REACH OUT TO AN NCI SBIR PROGRAM DIRECTOR



**Michael Weingarten, MA**  
*Director*  
NCI SBIR Development Center



**Greg Evans, PhD**  
*Lead Program Director*  
Cancer Biology, E-Health,  
Epidemiology, Research Tools



**Deepa Narayanan, MS**  
*Lead Program Director*  
Imaging, Clinical Trials, Radiation  
Therapy, Investor Initiatives



**Kory Hallett, PhD**  
*Lead Program Director*  
Immunotherapy, Biologics,  
and Program Analysis



**Jian Lou, PhD**  
*Program Director*  
In-Vitro Diagnostics, Theranostics,  
early-stage drug development,  
Bioinformatics, Investor Initiatives



**William Bozza, PhD**  
*Program Director*  
Biologics, Protein Therapeutics,  
Regulatory (CMC)



**Jonathan Franca-Koh, PhD, MBA**  
*Program Director*  
Cancer Biology, Biologics, Small  
Molecules, Cell Based Therapies,  
Phase IIb Bridge



**Nancy Kamei, PharmD, MBA**  
*Program Director*  
Cancer Therapeutics



**Monique Pond, PhD**  
*Program Director*  
Biologics, Research Tools and  
Regulatory Resources



**Amir Rahbar, PhD, MBA**  
*Program Director*  
In-Vitro Diagnostics, Biologics,  
Therapeutics, Proteomics



**Patricia Weber, DrPH**  
*Program Director*  
Digital Health, Therapeutics,  
Biologics, Resources Workshop



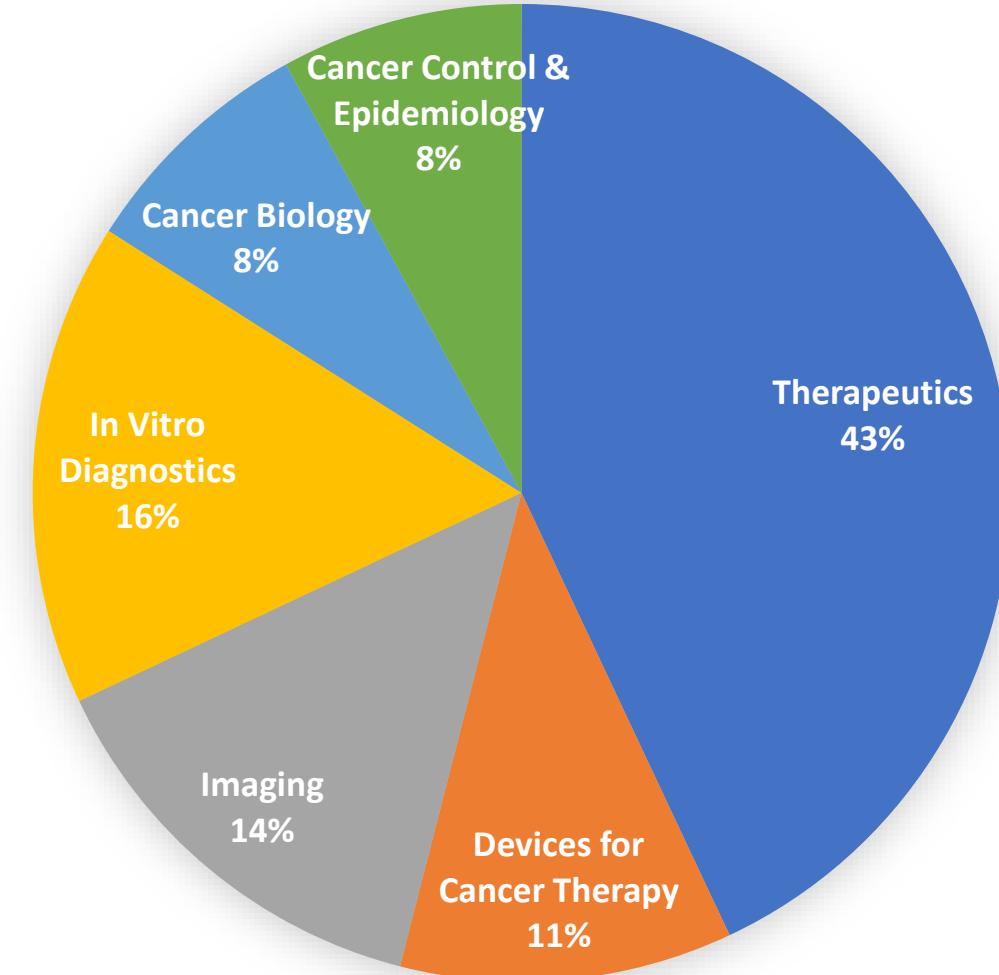
**Ming Zhao, PhD**  
*Program Director*  
Cancer Diagnostics & Therapeutics,  
Cancer Control & Prevention, Molecular  
Imaging, Bioinformatics, Stem Cells

**Contact us to get started!**

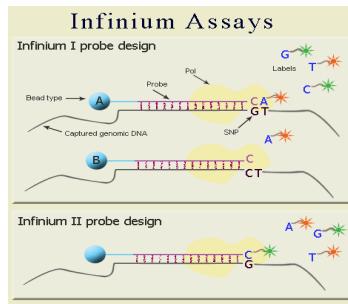
Send your Specific Aims page to [ncisbir@mail.nih.gov](mailto:ncisbir@mail.nih.gov) and we will help you set up a call with one of our program directors!

# NCI SBIR/STTR PORTFOLIO (n=475)

- \$173M in FY19 for SBIR/STTR awards
- 86% Grants, 14% Contracts



# SUCCESS STORY: ILLUMINA

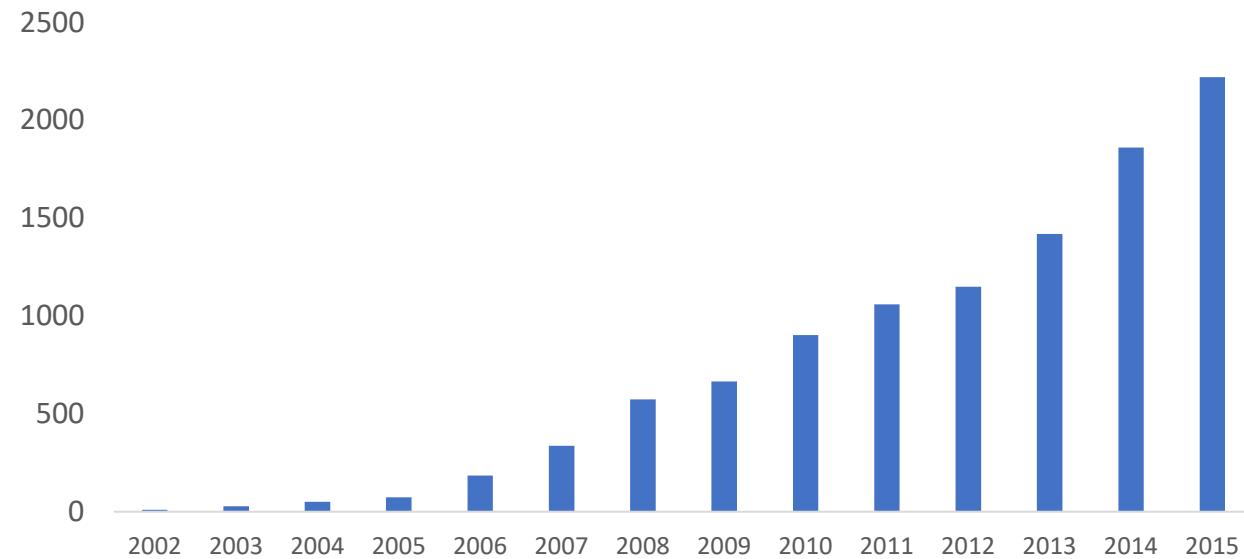


**Infinium - \$3.5B Sales**

**Infinium genotyping used for:**

- All of Us Research Program (NIH)
- 23 & Me
- Ancestry.com
- Basic and Clinical Research
- Agriculture Industry

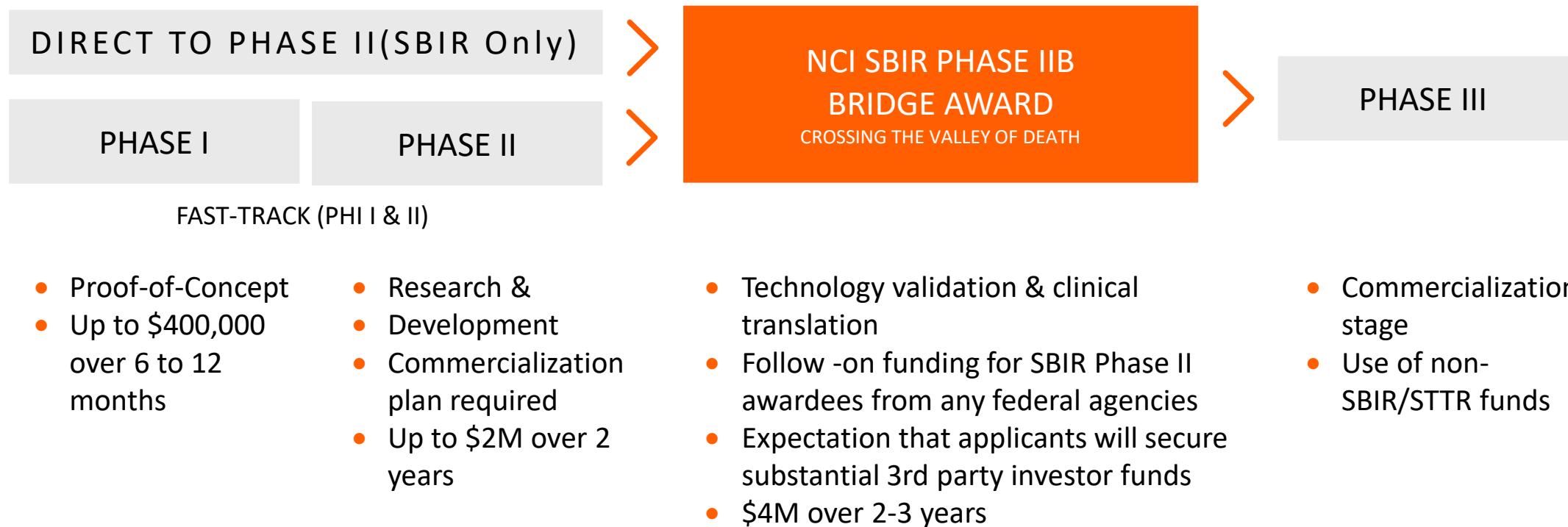
Illumina Revenue Growth from 2002 to 2015  
(in USD million)



“Illumina used SBIR funding to develop the base technology that went into the Infinium array.... At Illumina, we had at least one project for which we couldn't get SBIR funding because we lost eligibility, and that project never got done. So sometime, projects don't ever start without SBIR funding.”  
-Kevin Gunderson, PI on Illumina SBIR and creator of Infinium

# THREE-PHASE PROGRAM

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# SBIR & STTR FUNDING

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# BUDGET LIMITS

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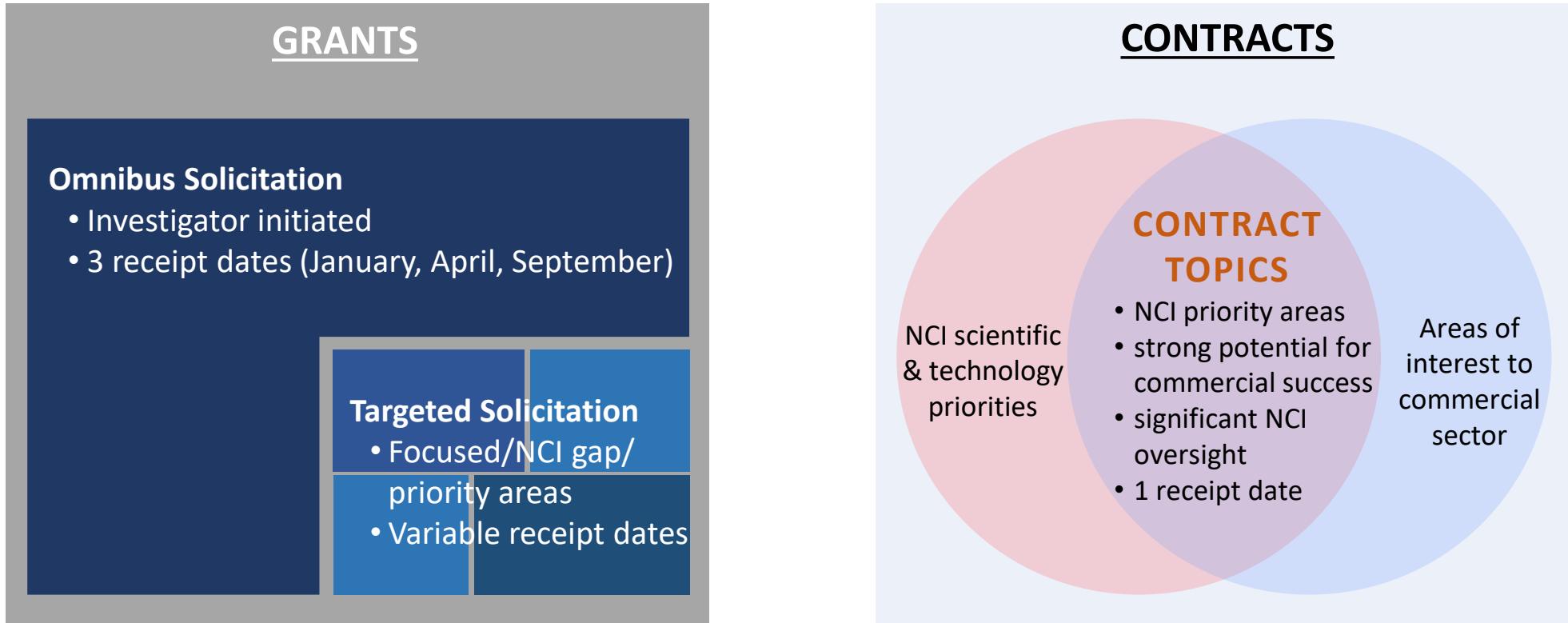
	Standard Award	Hard Cap	Waiver Cap*
Phase I	\$150,000	\$252,131	<b>NCI: \$400,000</b>
Phase II	\$1.0M	~\$1.68M	<b>NCI: \$2.0M</b>

\* Waiver cap is Institute specific. The waiver cap listed above is for NCI only.

For the list of current SBIR/STTR Waiver Topics for NCI, visit  
<https://sbir.nih.gov/sites/default/files/NIH%20Topics%20for%20Budget%20Waivers.pdf#page=3>

# FUNDING MECHANISMS

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# FUNDING OPPORTUNITIES

TITLE	SBIR FOA	STTR FOA	RECEIPT DATES
<b>Omnibus Solicitation</b>	PA-20-260 (General) PA-20-262 (Clinical Trial)	PA-20-265 (General) PA-20-261 (Clinical Trial)	
SBIR Technology Transfer (technology transfer out of NIH intramural labs)	PA-18-705 (SBIR only)	No STTR	<b>Standard Receipt Dates</b> <b>September 5;</b> <b>January 6;</b> <b>April 6</b>
Illuminating the Druggable Genome (IDG)	PA-19-034	PA-19-033	
Development of Highly Innovative Tools and Technology for Analysis of Single Cells	PA-20-047	PA-20-025	
SBIR IMAT (Innovative Molecular Analysis Technology) Development	PAR-18-303 (SBIR only)	No STTR	
Phase IIB Bridge Award	RFA-CA-20-033	Same as SBIR	~ August 2021
Small Business Transition Grant		RFA-CA-21-001	TBD
<b>Contract Solicitation</b>	<b>SBIR Only</b>	<b>No STTR</b>	<b>~ October</b>
<b>NCI SBIR Concept Award</b>	<b>TBD</b>	<b>No STTR</b>	<b>~ July</b>

# GRANT OMNIBUS SOLICITATION

- *Due Dates: September 5, January 5, and April 5*
- <https://sbir.nih.gov/funding>

Contact us to get started!

Send your Specific Aims page to [ncisbir@mail.nih.gov](mailto:ncisbir@mail.nih.gov) and we will help you set up a call with one of our program directors!

## SBIR & STTR Omnibus Solicitations for Grant Applications:

SBIR: PA-20-260 (General) PA-20-262 (Clinical Trial) –STTR: PA-20-265 (General) PA-20-261 (Clinical Trial)

### Application types allowed:

New (Phase I, Fast Track); Resubmission (all phases); Direct to Phase II (only SBIR)

**Applications for any topic within the NIH mission encouraged!**

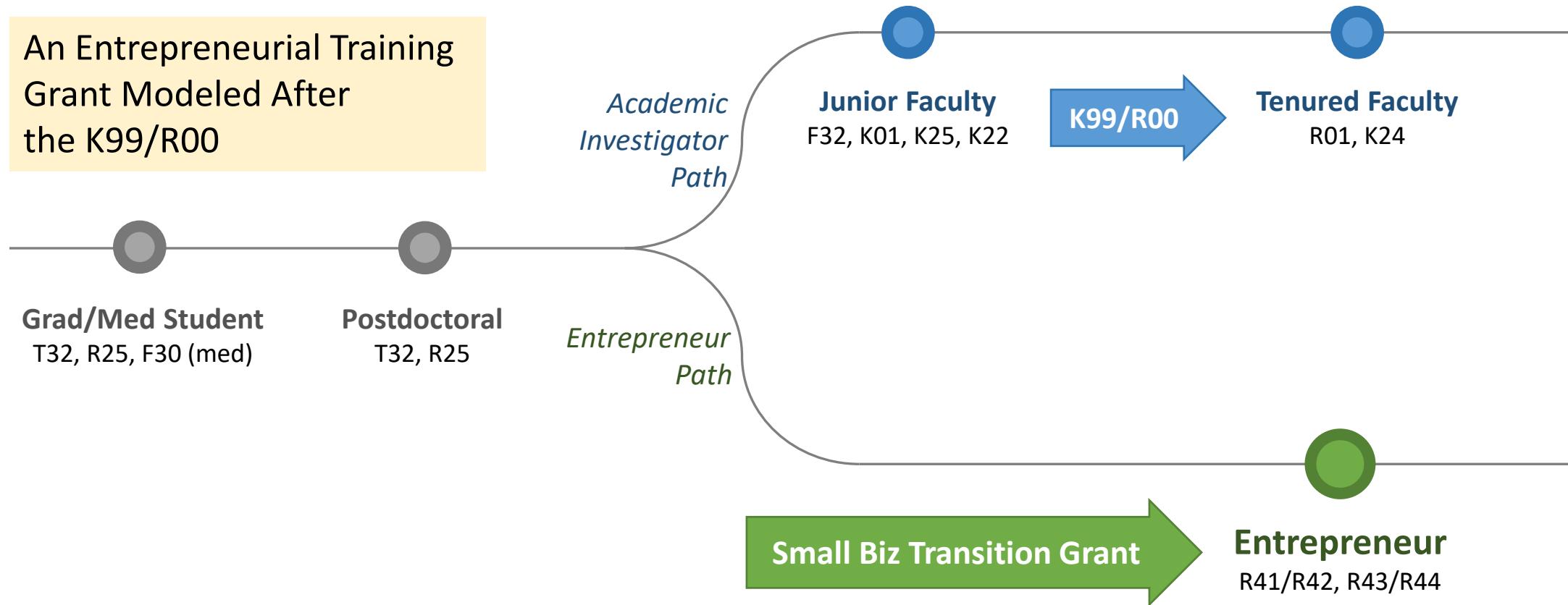
# PHASE IIB BRIDGE AWARD

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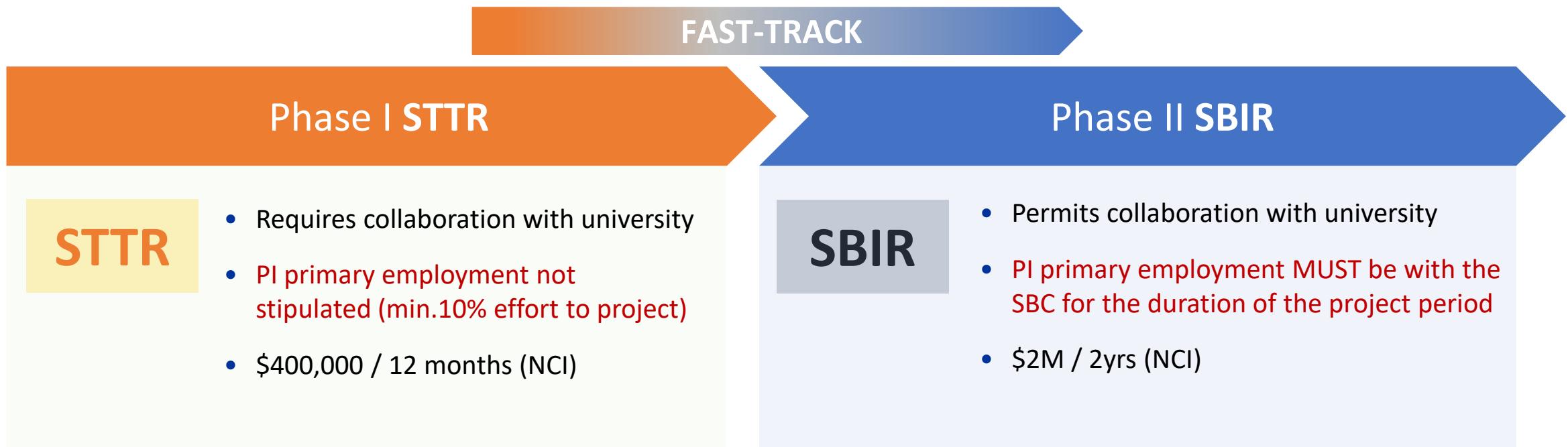
- Provides up to \$4M in additional funding over 2-3 years
- Technology validation and clinical translation
- Open to Phase II awardees from *any Federal agency* with projects relevant to NCI mission
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners *earlier in the development process*
- Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e.,  $\geq 1:1$  match)

# SMALL BUSINESS TRANSITION GRANT



# SMALL BUSINESS TRANSITION GRANT

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# SMALL BIZ TRANSITION GRANT

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## Eligibility

- Maximum 8-years from terminal degree
- Women and scientists from underrepresented groups encouraged

## Mentoring (special review criteria)

- Technical mentor commitment: cannot mentor more than one entrepreneur simultaneously
- Business mentor: can utilize mentoring programs, but must identify a lead mentor
- Expect the mentors to commit to a minimum of 2 hours/week AND I-Corps at NIH (Phase I)

## Technology Development is Critical

- Application MUST include milestones and go/no-go criteria for fast-track transition
- NCI is not guaranteeing training support to grantees whose technology fails

# CONTRACT

## SBIR CONCEPT AWARD

<https://sbir.cancer.gov/funding/concept>



- For transformative ideas
- Rare and pediatric cancers only
- \$300K for 1Yr
- Preliminary data are not required

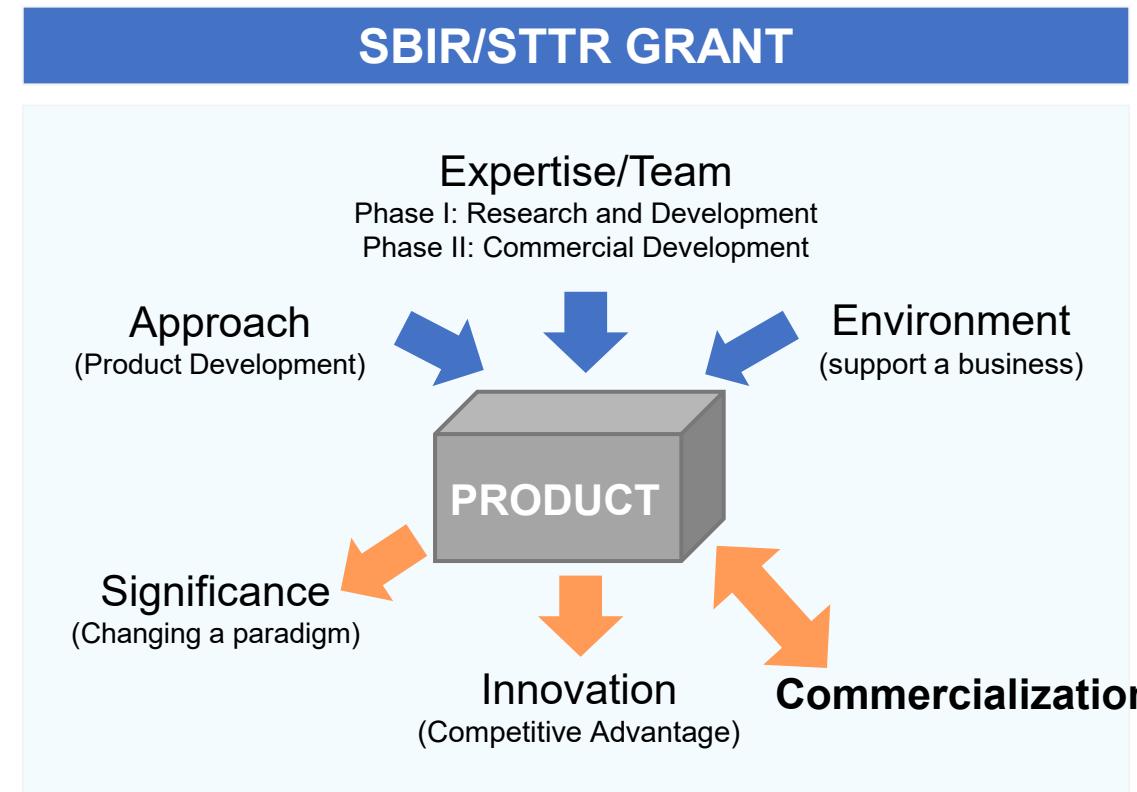
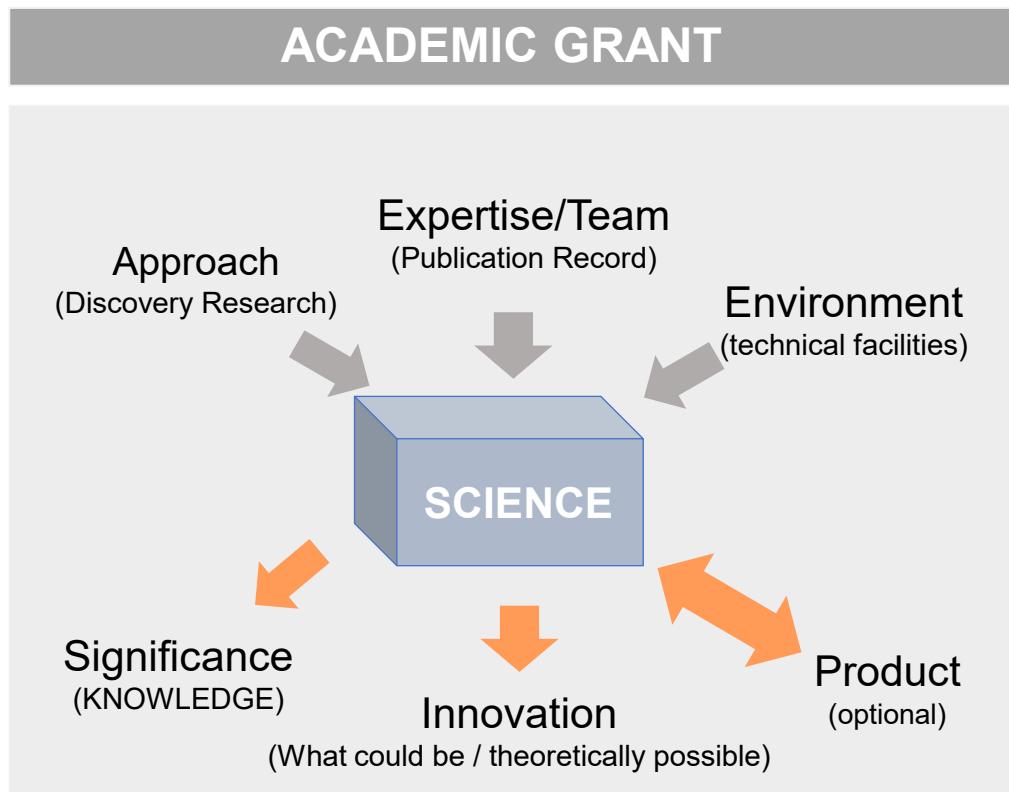
**Contact: Cherie Wells** ncioasbir@mail.nih.gov

**NEXT PROPOSALS DEADLINE: TBD**

# ABOUT SBIR & STTR

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# SBIR/STTR: MILESTONE-DRIVEN DEVELOPMENT

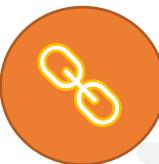


**Strong science is critical,  
but the proposal should focus on the product**

# NCI SBIR RESOURCES

## INVESTOR INITIATIVES PROGRAM

Connect companies to follow on funding  
Develop & maintain a network of investors and  
industry partners.



## I-CORPS @ NIH

Entrepreneurial Training Program  
Understand Value Proposition, Business  
Model and Stakeholders.



## RESOURCE WORKSHOPS

Educate and Connect companies with federal  
and non-federal commercialization Resources.



## EXECUTIVE ROUNDTABLE

Peer Mentoring Platform for C-Level  
Officers to share experience and expertise



## WEBINARS (PLAN)

Informational Webinars with content  
relevant to early-stage start-ups. Webinar  
content shared by peers.



## CARE (REGULATORY PROGRAM)

Connecting Awardees with Regulatory  
Experts at FDA  
Sharing FDA information with companies.



## MENTORING PROGRAM\*

Industry & experienced mentor program  
for start-ups



## TABA (NEEDS ASSESSMENT)

NIH Managed Technical and Business  
Assistance  
External Contractor to help assess company's  
gap/need areas.



# APPLICANT ASSISTANCE PROGRAM (AAP)

- AAP is a **FREE** Application preparation ASSISTANCE program.
- Program goal:  
Provide a **mentor** for applicants with great technology, but little NIH experience and limited NIH experience in their network.
- Three rounds per year leading up to each Omnibus due date
- <https://sbir.cancer.gov/aap>

AAP PROVIDES	AAP DOES NOT PROVIDE
Phase I SBIR/STTR application preparation support and review	Grant writer
Specific Aims page review and advice	Research plan development
Submission process coaching	Small business registration or NIH application submission services

# GET IN TOUCH WITH US!

- **CONTACT NCI SBIR PROGRAM BEFORE YOU APPLY.**
- **SEND US YOUR SPECIFIC AIMS PAGE.**
- Web: <https://sbir.cancer.gov>  
Email: [ncisbir@mail.nih.gov](mailto:ncisbir@mail.nih.gov)  
Twitter: [@NCISBIR](#)  
LinkedIn: <http://bit.ly/ncisbirlinkedin>

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NCI SBIR provides funding, mentoring & networking assistance for small businesses with next-generation cancer technologies.

## o NCI Funding during the COVID-19 Public Health Emergency

Due to the potential impact of the declared public health emergency caused by COVID-19, the NIH has issued multiple guide notices, including notice on late applications. If your business is affected by COVID-19, check the list of available measures on our [Notices Page](#).

For updates on NCI extramural funding activities, please check [NCI Director Dr. Norman E. Sharpless' post](#) on the NCI Bottom Line blog.

## o What are the NCI SBIR & STTR Programs?

The SBIR & STTR Programs are one of the largest sources of early stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities.

[Learn more about the programs >](#)

## o Resources For



## o Sign up

Sign up for the latest funding opportunities and events information from NCI SBIR Development Center.

Email:

## o Latest Announcements

### [New Supplement for Technologies Adapted for COVID-19](#)

The NCI SBIR Development Center is issuing a [Notice of Special Interest \(NOSI\)](#) to highlight the urgent need for the development of prophylactic, therapeutic and diagnostic for COVID-19. The NOSI will be issued in the fall of 2020.

# THANK YOU

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## CONTACT INFO

NCI SBIR DEVELOPMENT CENTER

[ncisbir@mail.nih.gov](mailto:ncisbir@mail.nih.gov)

240.276.5300

