

DEC 3, 2021 | NCI TRP WEBINAR

NCI SBIR Funding for Drug Development



KORY HALLETT, PHD
LEAD PROGRAM DIRECTOR
NCI SBIR DEVELOPMENT CENTER

SBIR
DEVELOPMENT CENTER



ABOUT SBIR & STTR



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

Set Aside for FY20

SBIR 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&D budget > \$100M</i>	\$157M (3.2%)
STTR 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&D budget > \$1B</i>	\$22M (0.45%)
Total		\$1.18B for NIH \$179M for NCI

CRITICAL DIFFERENCES

SBIR		STTR
<u>Permits</u> research institution partners (e.g., universities)	PARTNERSHIP	<u>Requires</u> research institution partners (e.g., universities)
Small business may outsource ~33% of Phase I activities and 50% of Phase II activities	DIVISION OF LABOR	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)
The PD/PI's primary employment (i.e., >50%) MUST be with the SBC for the duration of the project period	PI INVOLVEMENT	PI primary employment not stipulated (min.10% effort to project)

The award is ALWAYS made to the small business concern.

WHO ARE SBIR/STTR APPLICANTS?



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



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?



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 //

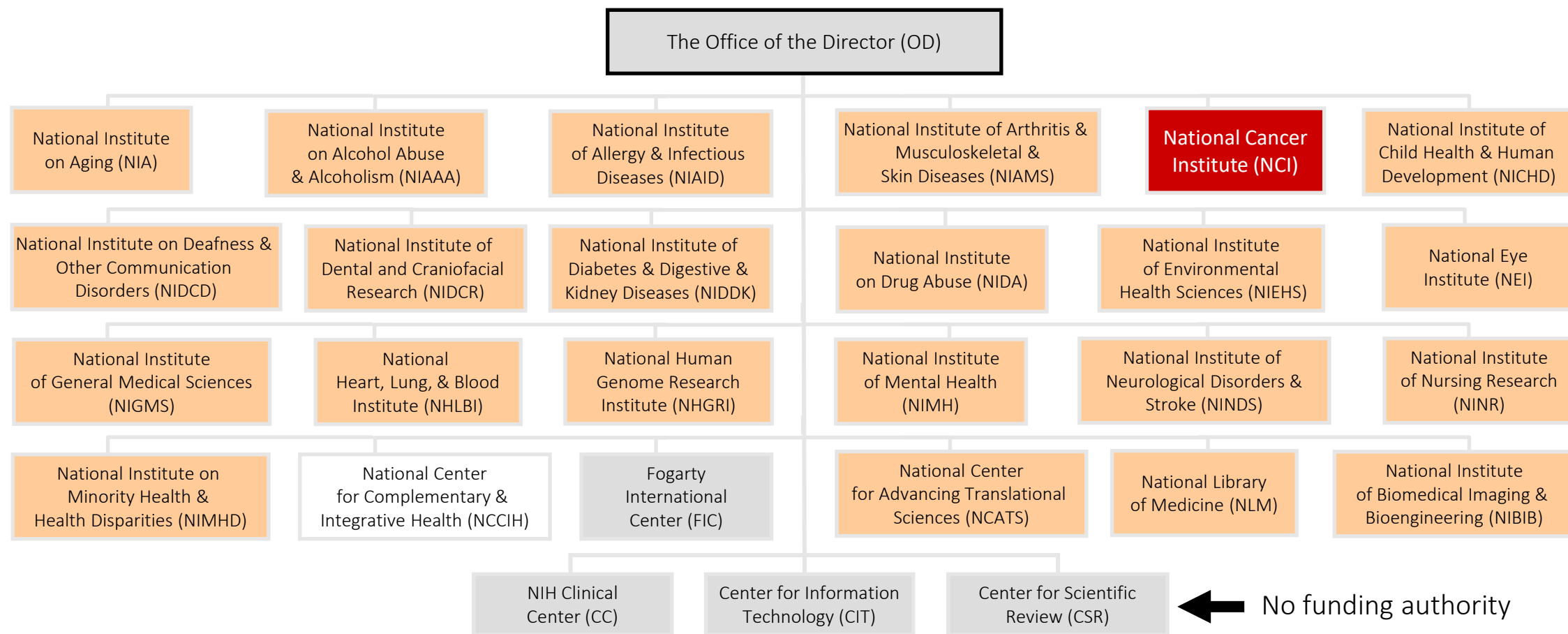
Every application is rigorously assessed by NIH Peer Review system.



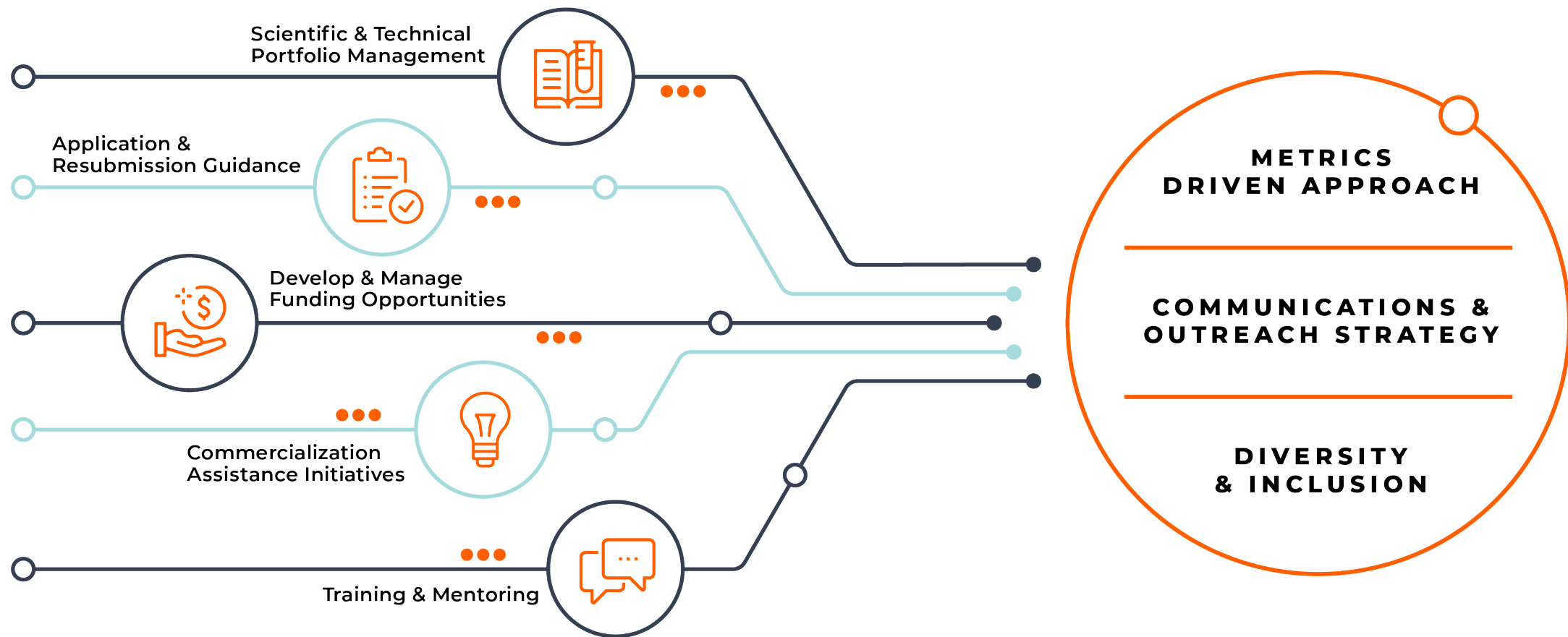
Helps provide leverage in attracting additional funding or support //

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
Immunotherapeutics, Biologics,
and Program Analysis



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



Nancy Kamei, PharmD, MBA
Program Director
Cancer Therapeutics



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



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



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



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



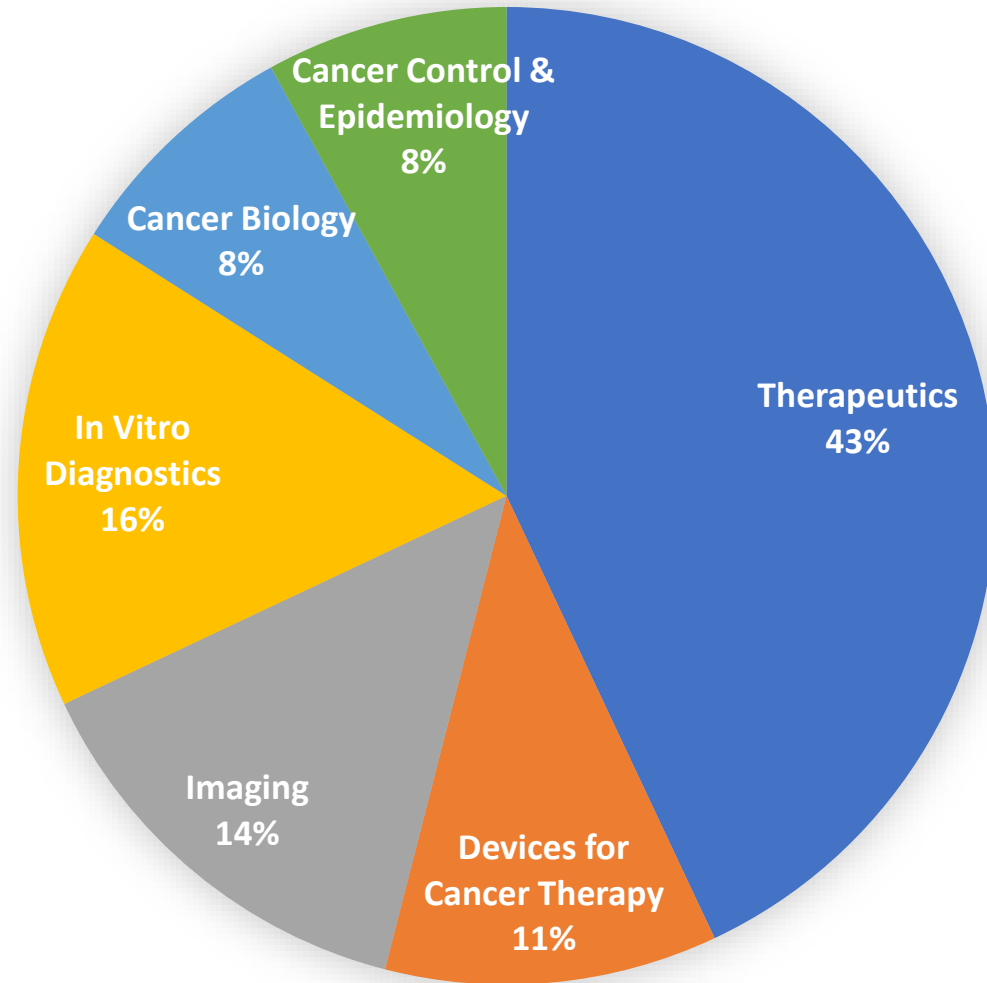
Ming Zhao, PhD
Program Director
Cancer Diagnostics & Therapeutics,
Cancer Control & Prevention, Molecular
Imaging, Bioinformatics, Stem Cells

Contact us to get started!

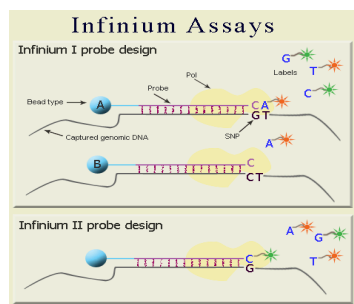
Send your Specific Aims page to ncisbir@mail.nih.gov and we will help you set up a call with one of our program directors!

NCI SBIR/STTR PORTFOLIO (n=475)

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



SUCCESS STORY: ILLUMINA

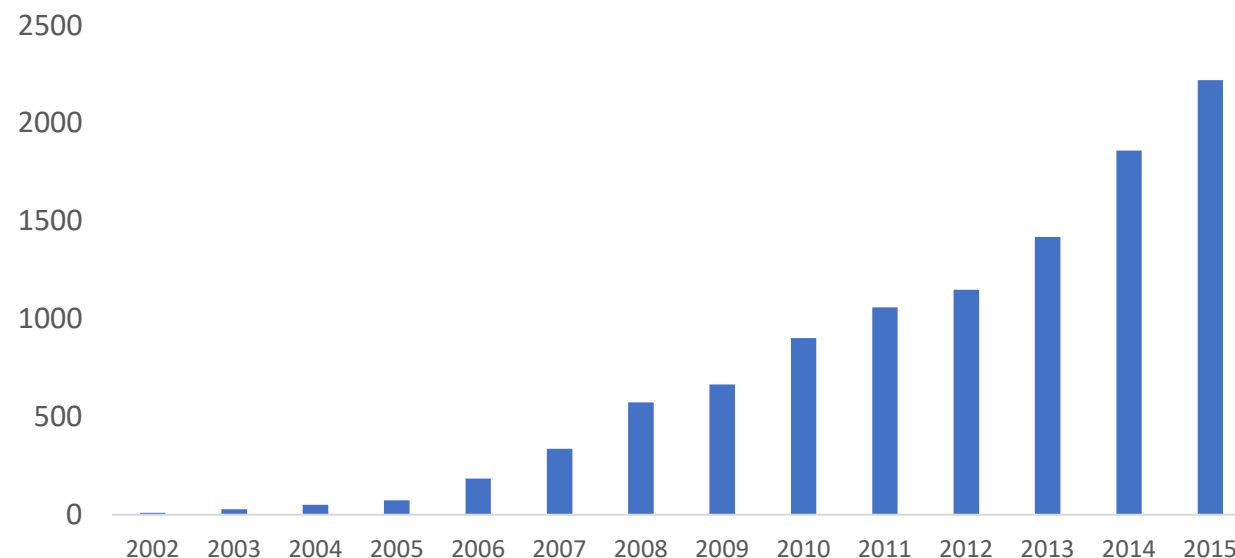


Infinium - \$3.5B Sales

Infinium genotyping used for:

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

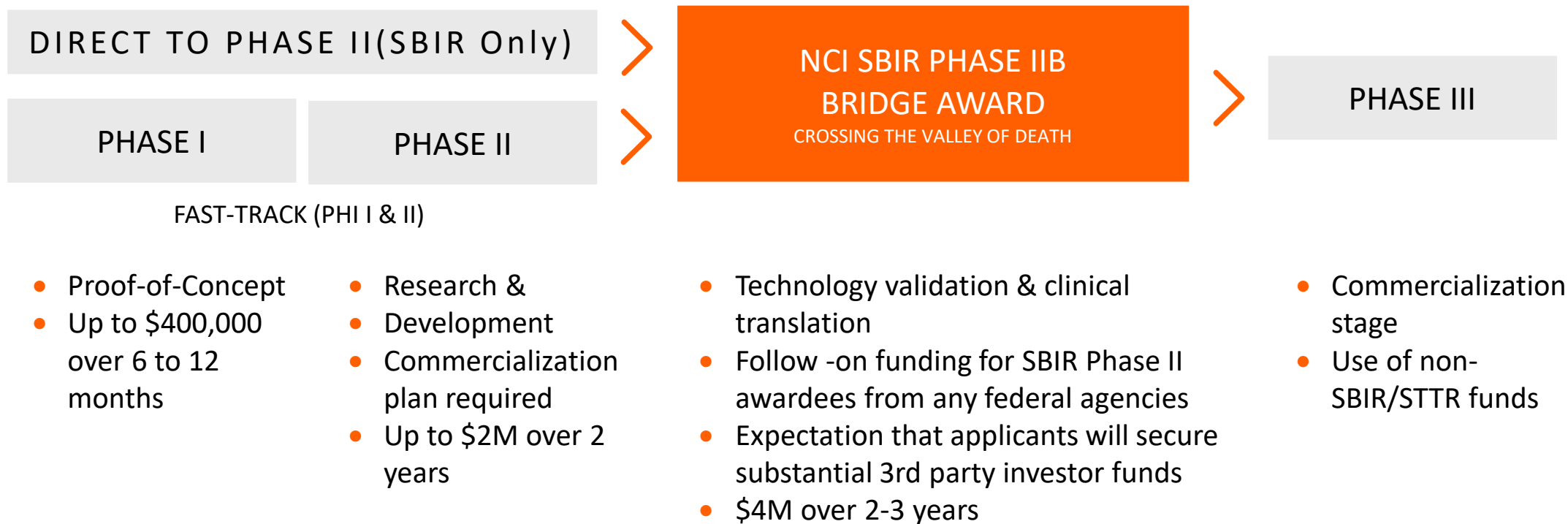
Illumina Revenue Growth from 2002 to 2015
(in USD million)



“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



SBIR & STTR FUNDING

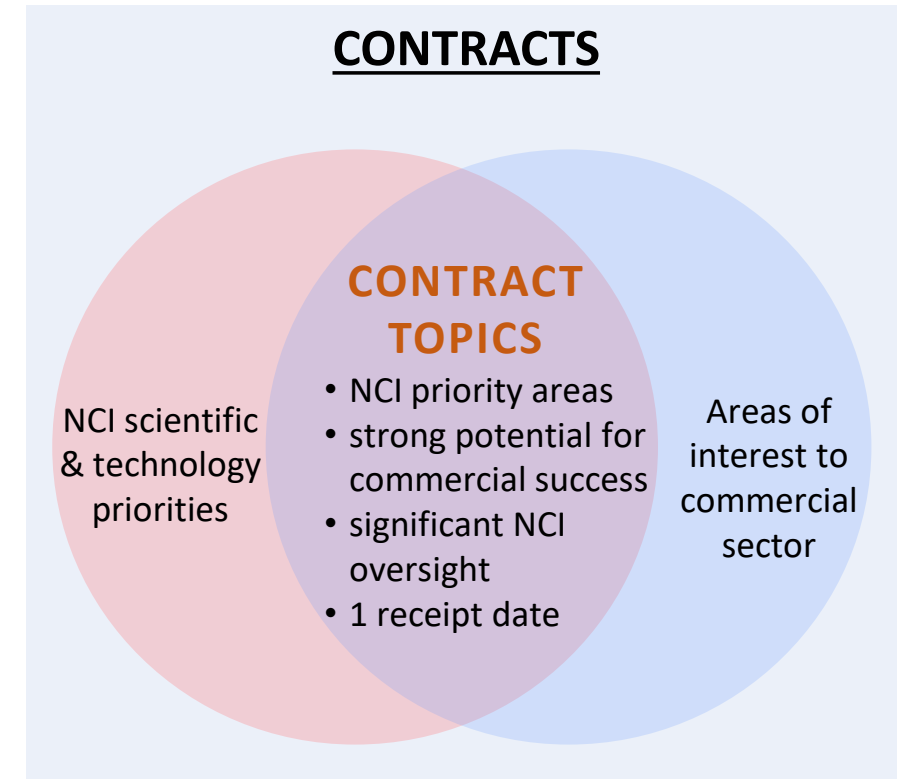
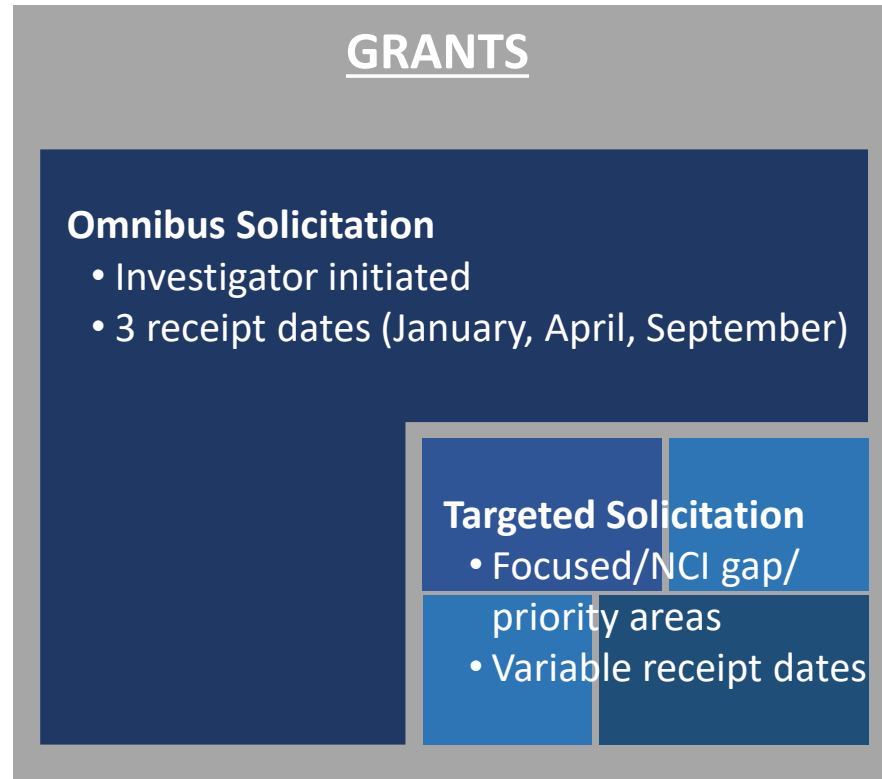
BUDGET LIMITS

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

* 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_Topics_for_Budget_Waivers.pdf#page=3

FUNDING MECHANISMS



FUNDING OPPORTUNITIES

TITLE	SBIR FOA	STTR FOA	RECEIPT DATES
Omnibus Solicitation	PA-20-260 (General) PA-20-262 (Clinical Trial)	PA-20-265 (General) PA-20-261 (Clinical Trial)	Standard Receipt Dates September 5; January 6; April 6
SBIR Technology Transfer (technology transfer out of NIH intramural labs)	PA-18-705 (SBIR only)	No STTR	
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
Contract Solicitation	SBIR Only	No STTR	~ October
NCI SBIR Concept Award	TBD	No STTR	~ July

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 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

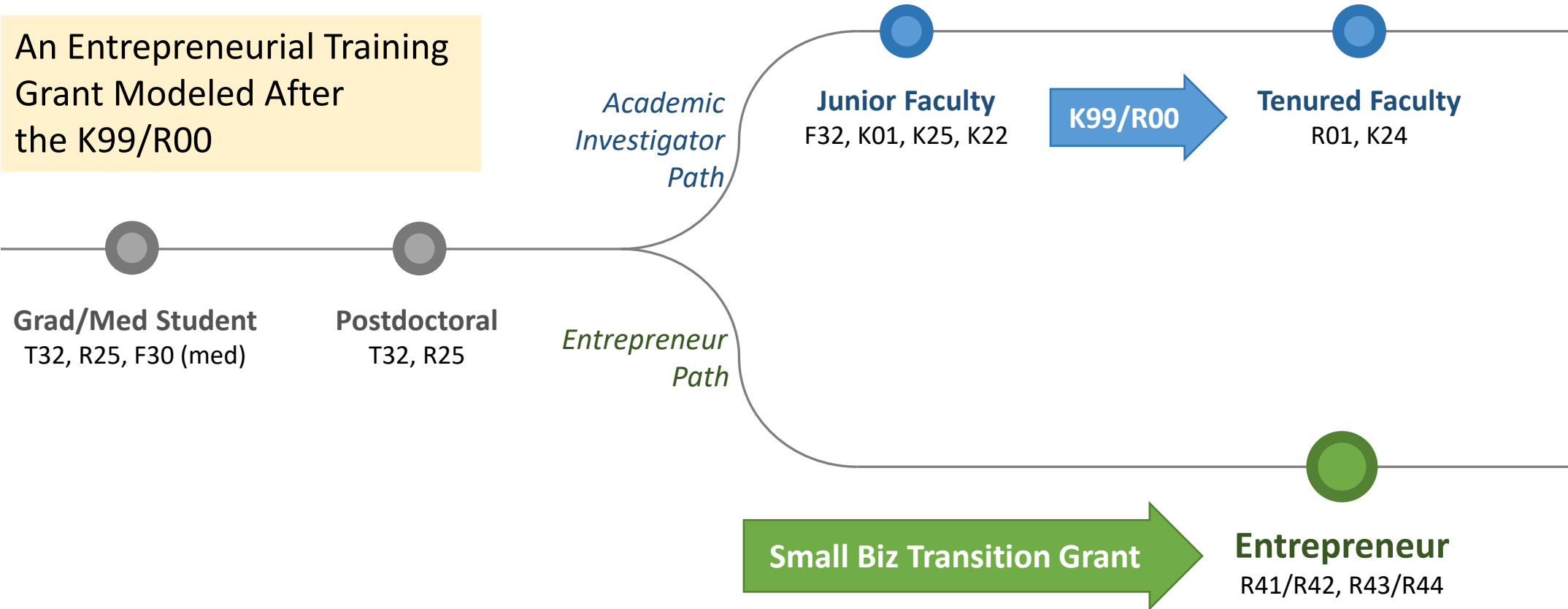
[RFA-CA-20-033](#)



- 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

An Entrepreneurial Training Grant Modeled After the K99/R00



SMALL BUSINESS TRANSITION GRANT

FAST-TRACK

Phase I STTR

STTR

- Requires collaboration with university
- PI primary employment not stipulated (min.10% effort to project)
- \$400,000 / 12 months (NCI)

Phase II SBIR

SBIR

- Permits collaboration with university
- PI primary employment **MUST** be with the SBC for the duration of the project period
- \$2M / 2yrs (NCI)

SMALL BIZ TRANSITION GRANT

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

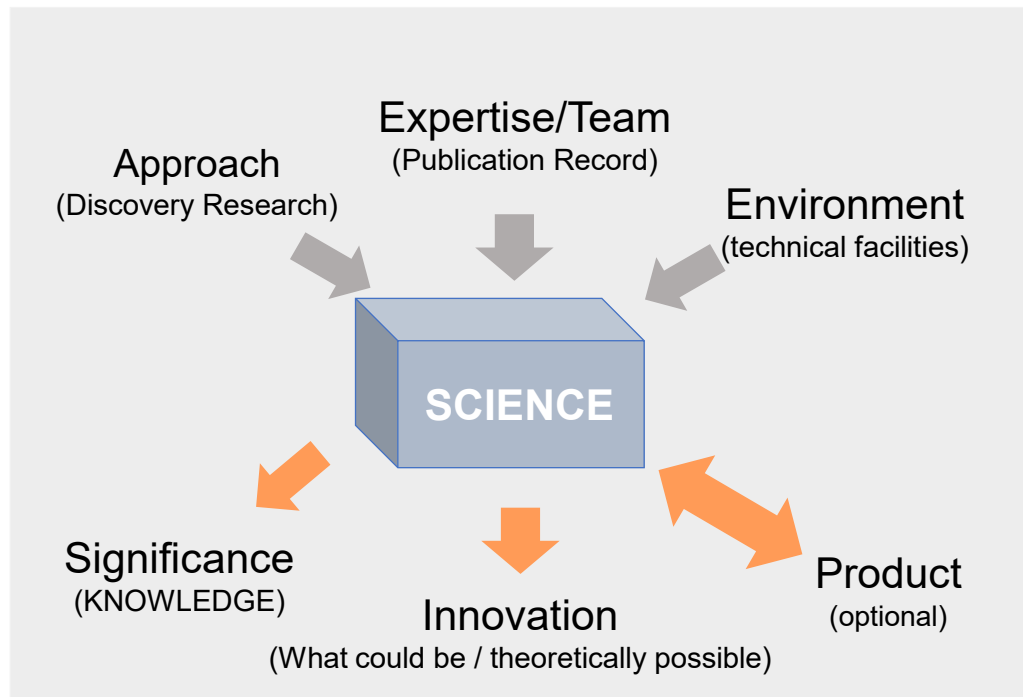
Contact: Cherie Wells ncioasbir@mail.nih.gov

NEXT PROPOSALS DEADLINE: TBD

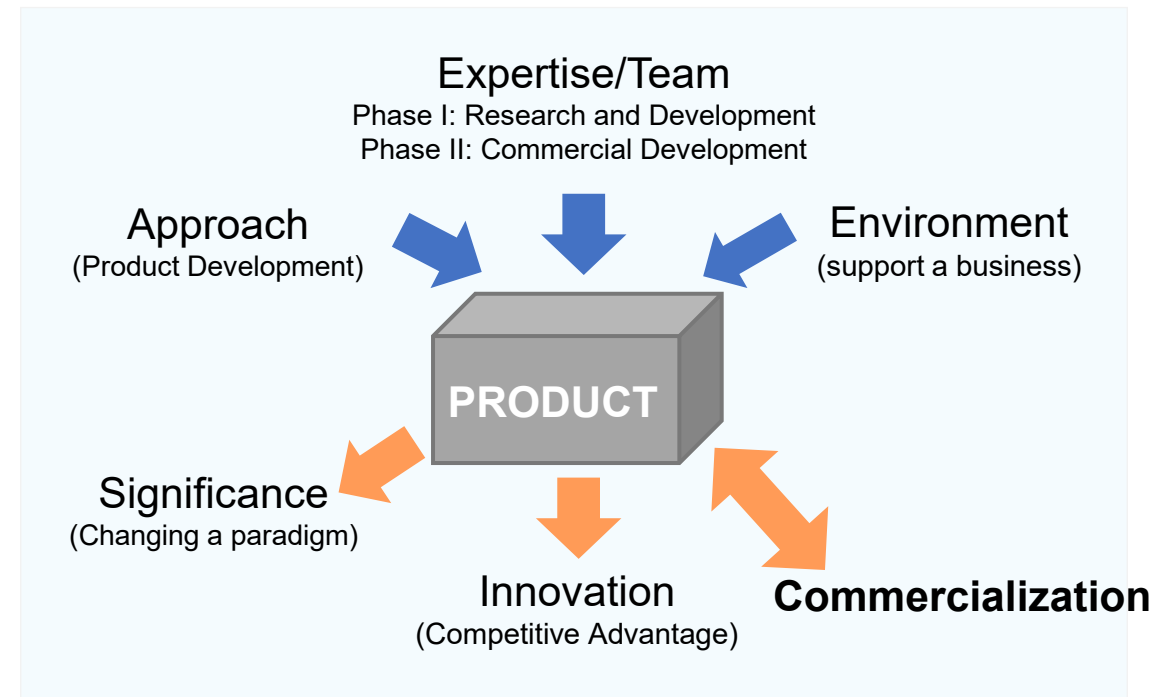
ABOUT SBIR & STTR

SBIR/STTR: MILESTONE-DRIVEN DEVELOPMENT

ACADEMIC GRANT



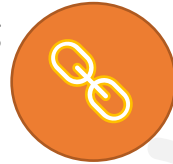
SBIR/STTR GRANT



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.



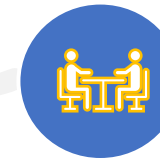
CARE (REGULATORY PROGRAM)

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



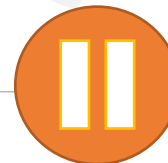
MENTORING PROGRAM*

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
Twitter: @NCISBIR
LinkedIn: <http://bit.ly/ncisbirlinkedin>

SBIR
DEVELOPMENT CENTER

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

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.

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 >](#)

Resources For

Sign up

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

Email:

Submit

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.

THANK YOU

CONTACT INFO

NCI SBIR DEVELOPMENT CENTER

ncisbir@mail.nih.gov

240.276.5300

