

May 17, 2022

# Federal Funding For Early-Stage Startups: Small Business Funding From The National Cancer Institute

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SBIR DEVELOPMENT CENTER  
NATIONAL CANCER INSTITUTE

**SBIR**

DEVELOPMENT CENTER



# SBIR/STTR Overview

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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

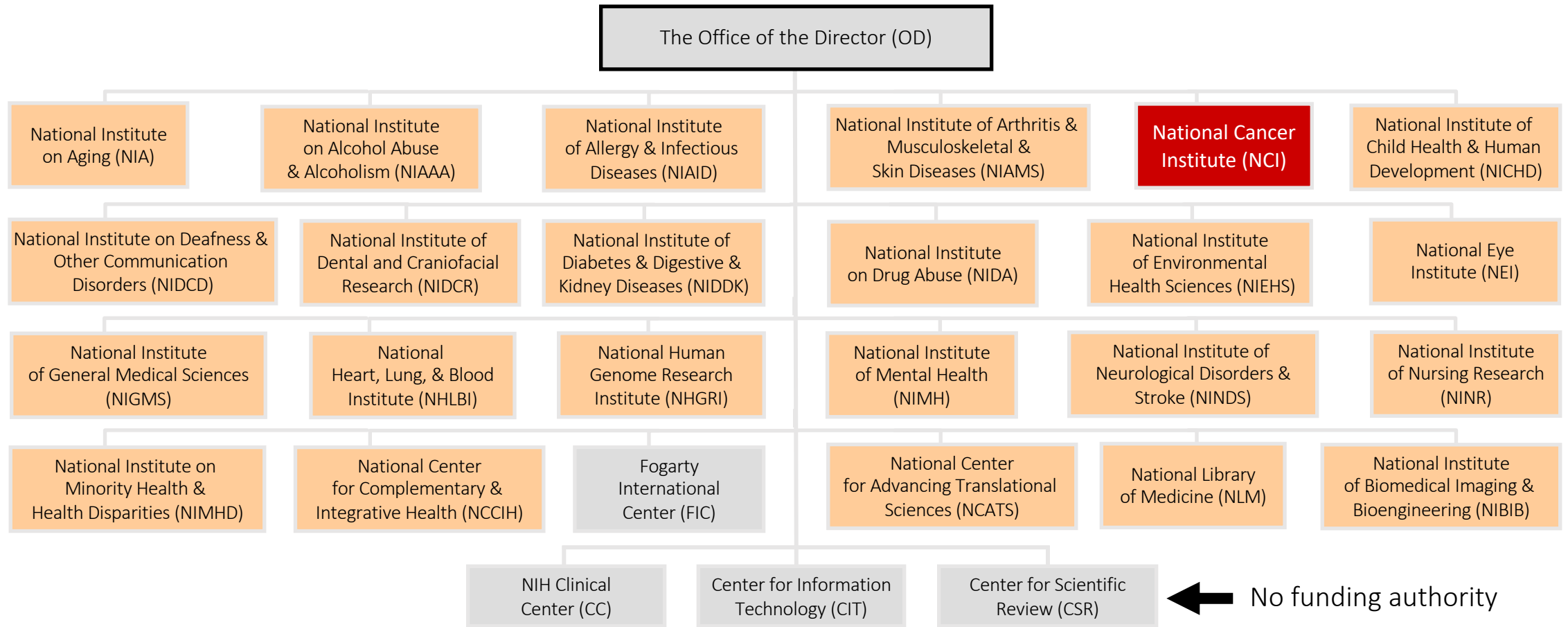


# CONGRESSIONALLY MANDATED PROGRAM

Set Aside for FY21

<p><b>SBIR</b> SMALL BUSINESS INNOVATION RESEARCH</p>	<p>Set-aside program for small business concerns to engage in Federal R&amp;D with the potential for commercialization <i>Federal agencies with an extramural R&amp;D budget &gt; \$100M</i></p>	<p><b>\$160M (3.2%)</b></p>
<p><b>STTR</b> SMALL BUSINESS TECHNOLOGY TRANSFER</p>	<p>Set-aside program to facilitate cooperative R&amp;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></p>	<p><b>\$22M (0.45%)</b></p>
<p>Total</p>		<p><b>\$1.2B for NIH</b> <b>\$182M for NCI</b></p>

# 27 INSTITUTES & CENTERS AT THE NIH



# NCI SBIR CORE ACTIVITIES



## CENTRAL OVERSIGHT

Administer all 400+ SBIR/STTR awards at the NCI



## GUIDANCE

Help prepare for application, resubmission, & discuss funding options



## OUTREACH

Attend conferences/workshops & visit organizations/universities to raise awareness of the program



## FUNDING

Seed emerging technology areas through targeted grant & contract funding opportunities



## NETWORKING

Maintain a network of investors and facilitate connections between portfolio companies & investors/strategic partners



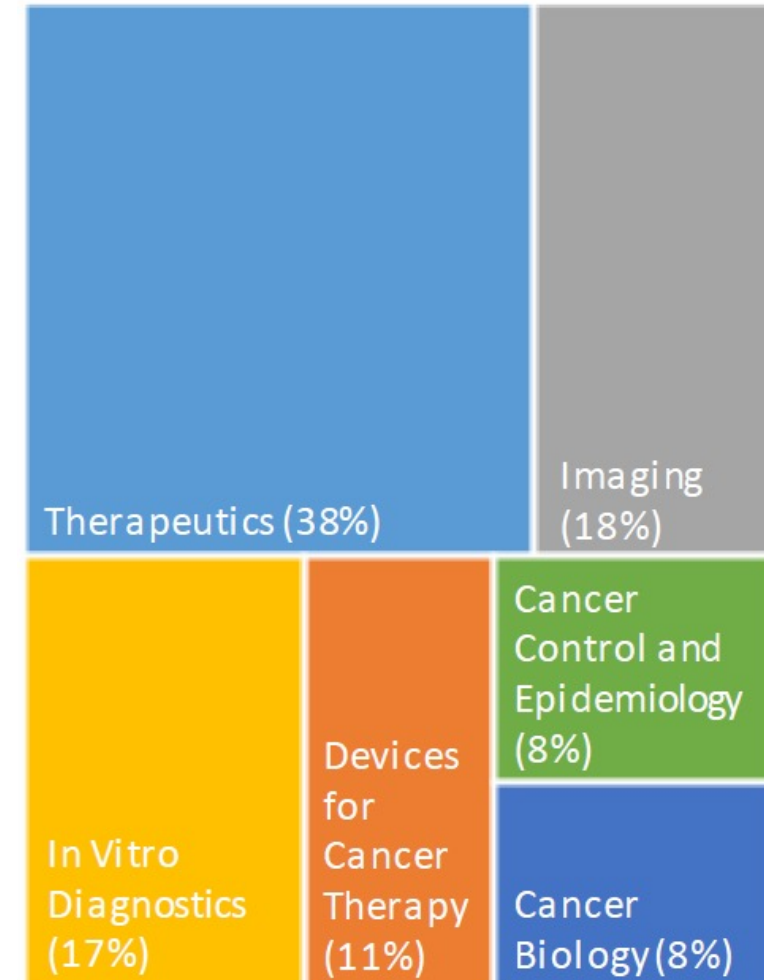
## TRAINING

Provide entrepreneurship training on key topics such as IP, regulatory strategy, & how to build a strong team

# NCI SBIR/STTR PORTFOLIO

- \$179M in FY2020 for SBIR/STTR awards
- 86% Grants and 14% Contracts in FY2020
- Oversee 475+ active SBIR/STTR awards
- Fund companies in preclinical and clinical stages

## What We Fund



# 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.)

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

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

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

Every application is rigorously assessed by NIH Peer Review system.

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

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

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# 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

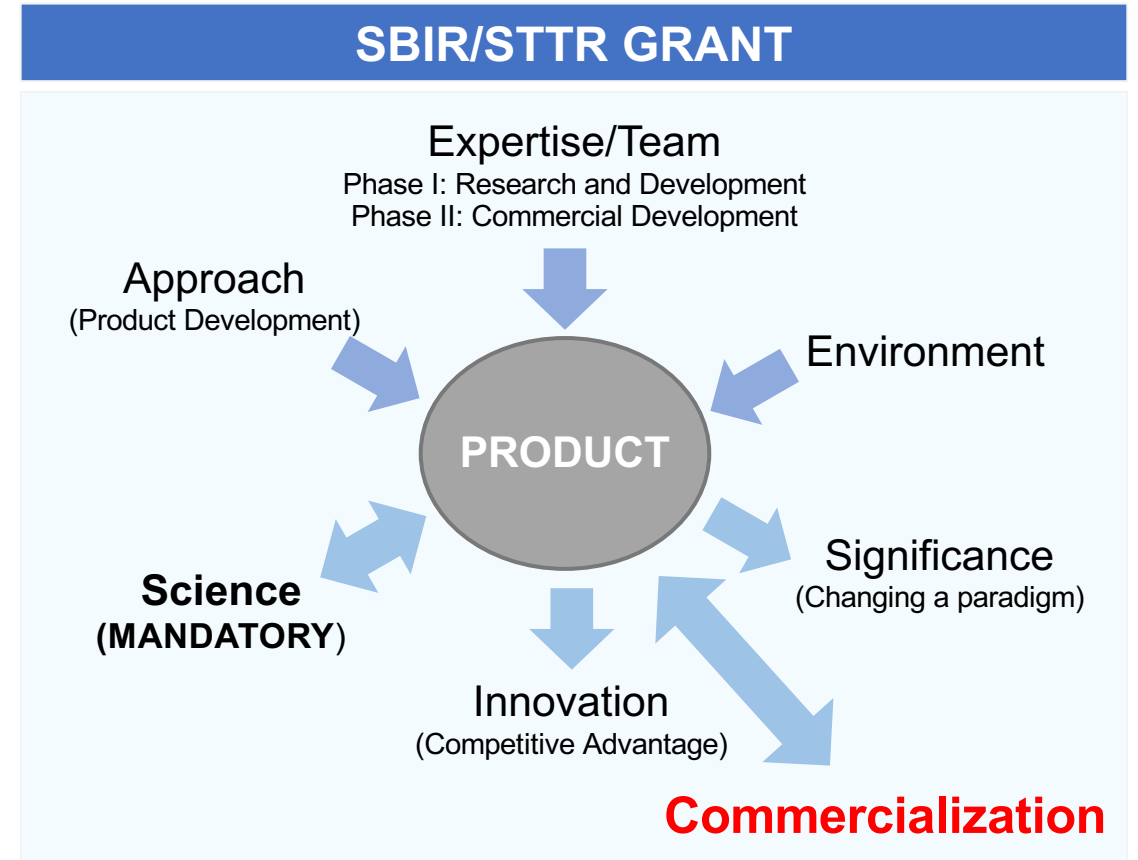
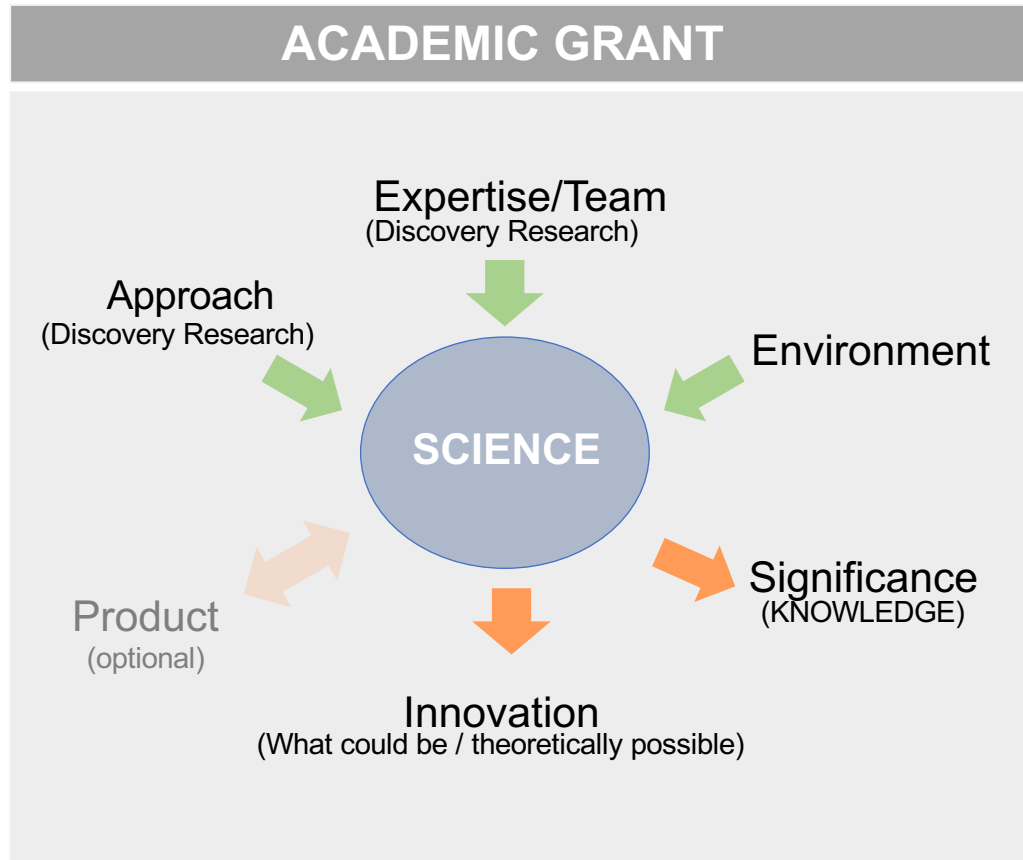
**OR**

> 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**)

# What's the difference between R01/R21 and SBIR/STTR?



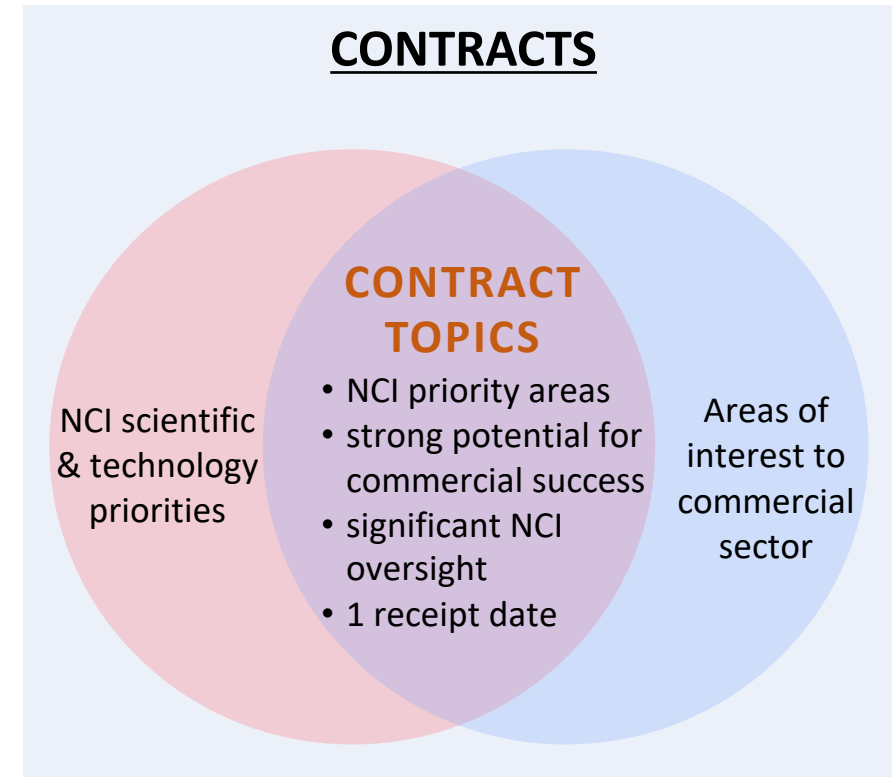
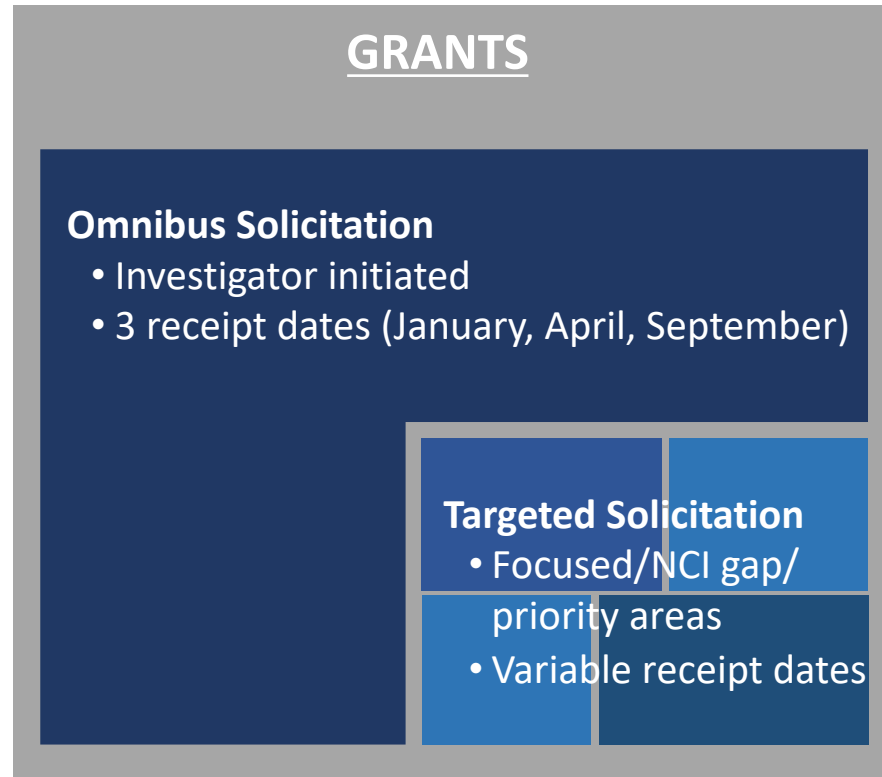
# What's the difference between SBIR and STTR?

SBIR		STTR
<p><u>Permits</u> research institution partners (e.g., universities)</p>	PARTNERSHIP	<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>	DIVISION OF LABOR	<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>	PI INVOLVEMENT	<p>PI primary employment not stipulated (min.10% effort to project)</p>

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

# FUNDING MECHANISMS

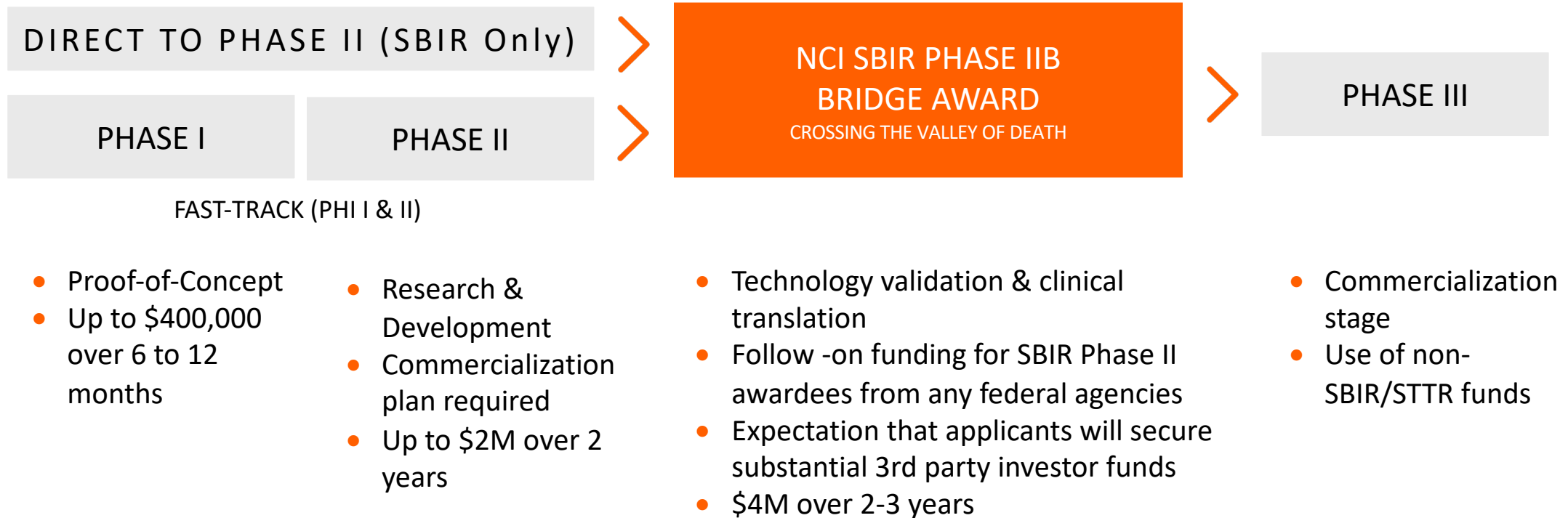
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# **SBIR/STTR FUNDING OPPORTUNITIES**

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# THREE-PHASE PROGRAM



# BUDGET LIMITS

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	NIH Standard Award	NIH Hard Cap	Waiver Cap*
Phase I	\$150,000	\$275,766	<b>NCI: \$400,000</b>
Phase II	\$1.0M	~\$1.84M	<b>NCI: \$2.0M</b>

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

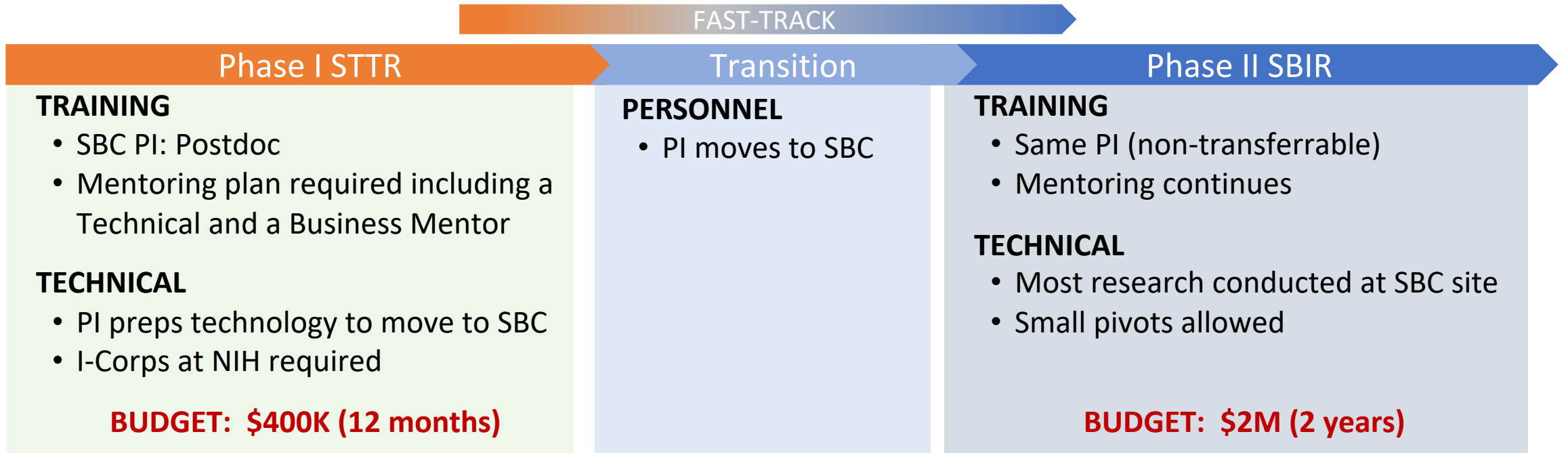
For the list of SBIR/STTR Waiver Topics for NCI (and other NIH Institutes), visit <https://bit.ly/19NCIwaiver>

# FUNDING OPPORTUNITIES

TITLE	SBIR FOA	STTR FOA	RECEIPT DATES
<b>Omnibus Solicitation (covers all of NIH)</b>	PA-21-259 (General) PA-21-260 (Clinical Trial)	PA-21-262 (General) PA-21-261 (Clinical Trial)	Standard Receipt Dates April 5; September 5; January 5
<b>Development of Highly Innovative Tools and Technology for Analysis of Single Cells</b>	PA-20-047	PA-20-025	
<b>Notice of Special Interest for Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings</b>	NOT-CA-21-062	NOT-CA-21-062	
<b>Technology Development for Single-Molecule Protein Sequencing</b>	PAR-21-247	No STTR	June 15, 2022; June 15, 2023
<b>Small Business Transition Grant for Early Career Scientists</b>	No SBIR	RFA-CA-22-017	August 22, 2022
<b>NCI SBIR Concept Award (Contract)</b>	75N91022R00006	No STTR	August 22, 2022
<b>NCI SBIR Phase IIB Bridge</b>	RFA-CA-22-025	No STTR	August 5, 2022
<b>[Coming Soon] Contract Solicitation</b>	Summer 2022	No STTR	~October 2022



# SMALL BUSINESS TRANSITION GRANT



# SMALL BUSINESS TRANSITION GRANT

## DUE DATES

Letter of Intent – July 22, 2022

Applications – August 22, 2022

[RFA-CA-22-017](#)

Participating Institutes: NCI, NIBIB, NIDA

- **Eligibility**
  - Maximum 8-years from terminal degree
  - Women and scientists from underrepresented groups encouraged
- **Mentoring (special review criteria)**
  - Working with NCI CCT to learn from K99/R00
  - 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



# PHASE IIB BRIDGE AWARD

[RFA-CA-22-025](#)



- 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)

# FY23 NIH/NCI CONTRACT TOPICS

Solicitation will be available here Summer 2022:

<https://sbir.cancer.gov/funding/contracts/currentcontracts>

Topic Title	Goal
Development of Senotherapeutic Agents for Cancer Treatment	Support the basic and pre-clinical development of senotherapeutic agents for use in research, neoadjuvant, adjuvant, or combination cancer therapy.
Non-invasive Device Technology Research & Development for Chemotherapy-induced Peripheral Neuropathy Management	Advance the development of innovative non-invasive device technologies to provide effective mitigation of CIPN in a noninvasive, cost-effective, accessible manner in the home-care setting.
Wearable Devices for Dosimetry of Radiopharmaceutical Therapy	Develop wearable technologies (e.g., dosimetry sensor-incorporated clothing) to allow radiopharmaceutical therapy dose to be continuously measured providing rich, time-based dose data for RPT agents that can be correlated with the patient's anatomy.
Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment	Improve the availability of new and/or better remote monitoring tools for patients and their clinical care teams during sensitive periods of treatment with a view to improved health-related Quality of Life and reduced costs associated with further hospital visits.
Technology Platforms for Circulating Tumor-Macrophage Hybrid Cells	Support the development of platforms to isolate, enrich, enumerate, and identify the cTMHCs in blood from cancer patients or animal models of cancer. This contract topic aims to enable thorough understanding of the biology of THMCs in metastasis and provide a novel means to remotely monitor cancer progression and metastasis.
Rapid and Affordable Point-of-Care HPV Diagnostics for Cervical Cancer Control	Advance the development of new alternatives for HPV testing to the market that are both in a form factor as well as price point that will enable self-testing programs to be established globally.
Translation of Novel Cancer-Specific Imaging Agents and Techniques to Mediate Successful Image-Guided Cancer Interventions	Support the translation of novel activatable agents and/or techniques for sensitive cancer detection in human subjects. Ideally, this would translate existing pre-clinical successes with activatable diagnostic probes to clinical tools that can detect small tumor cell clusters (~1mm <sup>3</sup> in volume) via imaging.
Digital Tools to Integrate Cancer Prevention Within Primary Care	Develop a digital platform that provides PCPs with validated cancer risk assessment tools, cancer prevention guidelines, and clinical recommendations based on a patient's risk factors to discuss with their patients.
Software to Evaluate Artificial Intelligence/Machine Learning Medical Devices in Oncology Settings	Stimulate the participation of small businesses in FDA's Medical Device Development Tool (MDDT) program to develop software tools for evaluating and monitoring AI/ML devices in oncology settings.

# 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.”



**Lori Hazlehurst, Ph.D.**

Professor, Pharmaceutical Sciences, West Virginia University  
President and Co-founder, Modulation Therapeutics

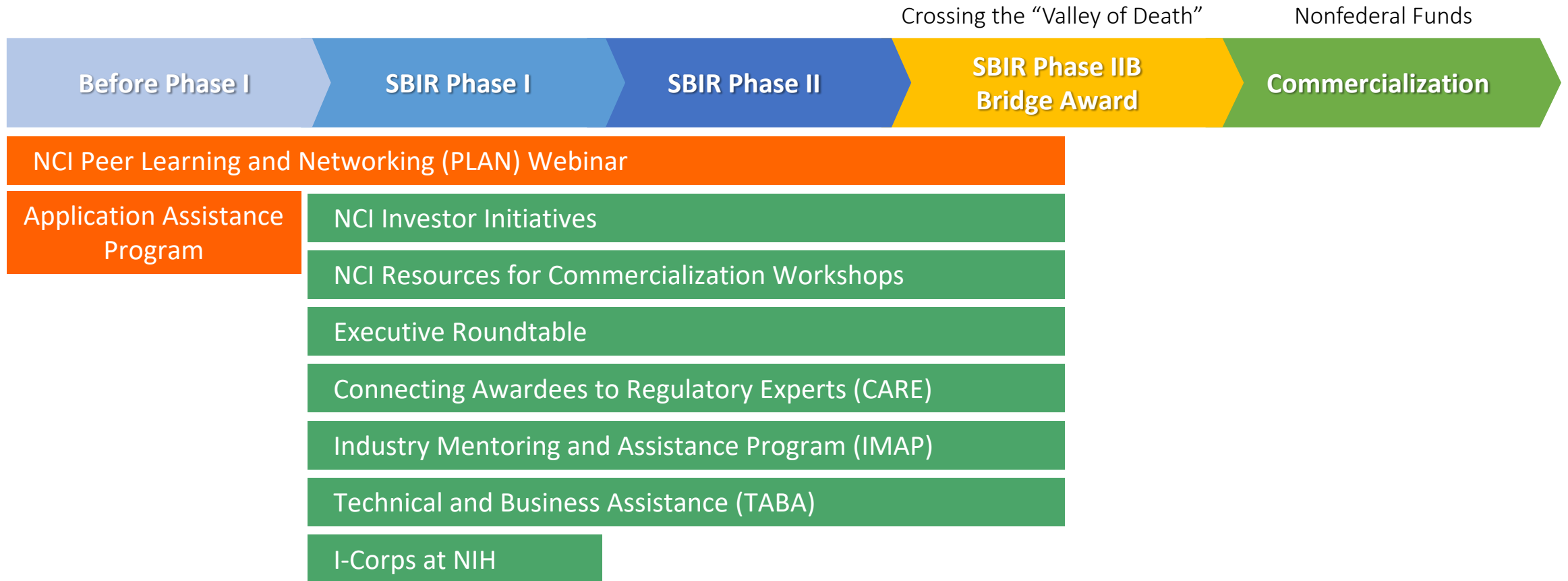
“My laboratory was working in drug development and it takes a long time to license a technology. It was hard to push forward with only R01 funding and we had neat technology, worth pursuing.”

# NON-FUNDING RESOURCES

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# NCI SBIR ASSISTANCE

<https://sbir.cancer.gov/resources>



# NIH APPLICANT ASSISTANCE PROGRAM

AAP is a **FREE** Application preparation **ASSISTANCE** program that is **10 weeks** in length.



## PROGRAM GOAL

Provide a **mentor** for applicants with great technology, but little NIH experience and limited NIH experience in their network.

## APPLICATION PERIOD

**NOW OPEN!** Closes May 23, 2022 at 5 p.m. ET

<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



# AAP ELIGIBILITY

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- **Simple eligibility criteria:**
  - **No previous NIH SBIR/STTR awards granted**
- **Particularly interested in applicants by individuals currently underrepresented in the biosciences** (not a requirement for program)
  - **Women-owned / Run businesses**
  - **Minority-owned / Run businesses**
  - **Small Businesses operating in an underrepresented (IDeA) state**

# I-CORPS AT NIH



- **Funding Opportunity Announcement (FOA):** PAR-22-073  
(next receipt date: November 15, 2022)
- Intensive **Entrepreneurial Immersion** course aimed at providing teams with skills and strategies to reduce commercialization risk
- Curriculum emphasizes **Reaching out to Customers** to test hypotheses about the market(s) for the technology
- Teams are expected to conduct over **100 interviews** in 8 weeks
- Format is focused on **Experiential Learning**
- NCI SBIR designed, launched, and manages the program for NIH
- Open to Phase I SBIR/STTR awardees from 24 Institutes at NIH and CDC

More information: <https://sbir.cancer.gov/icorps>

# APPLICATION TIPS

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# Getting Started



# Tip #1: START EARLY

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- **Read the solicitation & SF424 carefully**
- **Strong proposals take time to develop**
  - Refining your product
  - Gain access to equipment, facilities, other resources
  - Assemble a strong scientific team
  - Obtain letters of support
- **Complete the administrative registrations**
  - Five Required registrations (<https://sbir.nih.gov/infographic>)

Resources for New Applicants:  
<https://sbir.cancer.gov/resources/forapplicants>



# Tip #2: REFINE YOUR PRODUCT VISION

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- **Start informal discussions to clarify the product vision**
  - Technical experts, potential customers, investors, commercialization partners, and other stakeholders
- **Seek help from others with experience and insights**
  - Current/prior SBIR grantees
  - Academic collaborators with grant writing experience
  - Professional grant writers\*
  - **Engage with SBIR program staff for information on agency priorities, current NIH policies, etc.**
- **Before you Apply**
  - Review similar, currently-funded NIH SBIR/STTR projects <https://projectreporter.nih.gov/reporter.cfm>

# Tip #3: TALK TO A PROGRAM DIRECTOR

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

**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!



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



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



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



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



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



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



**Monique Pond, PhD**  
*Program Director*  
Biologics, Small Molecules, Therapeutic Devices, Digital Health, Regulatory Resources



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



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



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



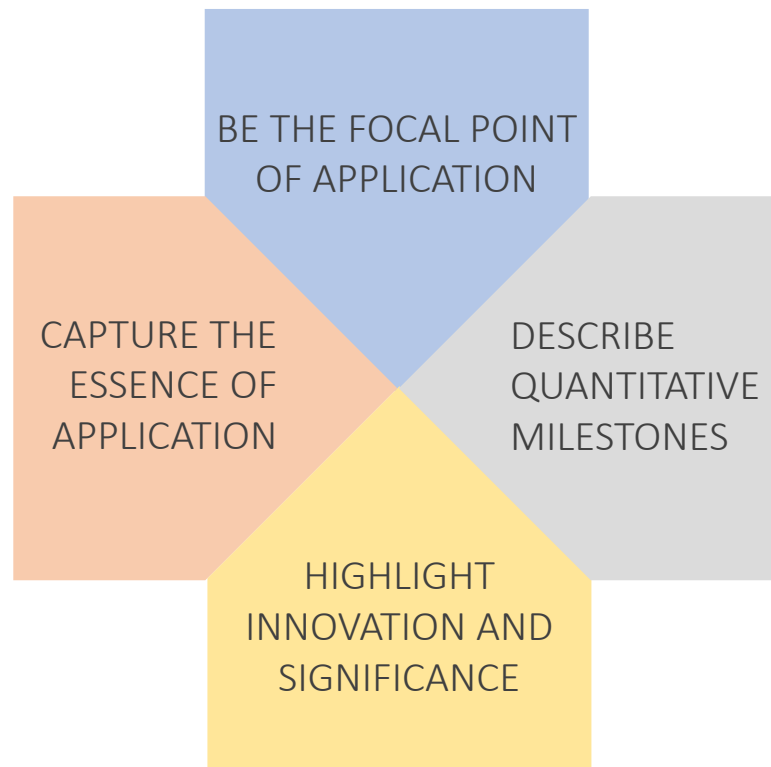
**Amir Rahbar, PhD, MBA**  
*Program Director*  
In-Vitro Diagnostics, Biologics, Therapeutics, Proteomics



**Joan Greve, PhD**  
*Program Director*  
Imaging, Biomedical Product Development and Translation, Workforce Development and Diversification

# SPECIFIC AIMS PAGE

## SPECIFIC AIMS



**SPECIFIC AIMS PAGE ADVICE**

**The Aims Page**

The specific aims page is a critical page in an SBIR/STTR application. The aims page should be treated as a stand-alone page from which a reviewer can gain a reasonable understanding of the project's critical components without reading any other parts of the application. Applicants are only allowed one page for their specific aims. Applicants are assigned to 3 or 4 primary reviewers who are responsible for initial scoring and acting as primary discussants during the larger peer review panel. Often the primary reviewers are the only members of the peer review panel to read the application in its entirety. For applications that are discussed, the final priority score will be set at discussion by a panel of 30+ peer reviewers. Many of the peer reviewers will likely only read the aims page of an application. Therefore, it is critical that the aims page clearly convey why this application should be selected out of the roughly thousand applications received by NCI SBIR the program annually.

The first half to two-thirds of the aims page should cover key background information. The background should clearly convey three things:

1. **The product.** A clear product description is critical to an SBIR application and is often a key difference separating an SBIR application from a basic science or discovery science application. SBIR grants are intended primarily for product development, whereas basic/discovery grants are primarily intended for the advancement of knowledge.
2. **The significance.** A problem/proposed solution format often works well to convey significance. If there is an unmet clinical need, it will help the application for this need to be clearly stated.
3. **The innovation.** How will the product change the current paradigm or practice? How will those affected by cancer benefit from this product being commercially available? The aims page should convey this information as well as provide some textual highlights of the preliminary data as supporting evidence that the product will perform as proposed.

The second half to one-third of the aims page should state your specific aims. An often-successful format for the aims is one in which a clear bulleted aims statement is made, followed by key assays and models proposed to complete each aim, with appropriate milestones. It is critical that each aim have clearly articulated success criteria. Whenever reasonable, the success criteria should be defined by quantitative metrics. However, in cases where only qualitative success criteria are appropriate, they should be clearly stated. For fast-track applications, a go/no-go decision at the end of the phase I component should be obvious.

A statement of next steps is often a nice way to wrap-up an aims page. A statement about what will be accomplished during phase II (for phase I applications) or after the award ends (for phase II applications) allows reviewers to judge if the aims will adequately prepare the project for the next step. A statement of next steps also provides an opportunity to show the reviewers that the company is focused on moving the product forward on a path to commercialization.

Overall, an SBIR application should focus on the product. Each section of the application should focus on how the proposed work will improve product commercialization. Successful SBIR/STTR applications clearly describe how the product will benefit a population affected by cancer, and identify the customer.

**IMPORTANT:** This guide page is meant to be used as advice for applicants and is not intended as program requirements. This advice page was developed based only on the opinions of several NCI SBIR Program Directors and successful SBIR awardees.

### BACKGROUND:

Product  
Innovation  
Significance

### AIMS:

Goals-based statements  
Key assays and models  
Quantitative milestones

### CONTEXT:

These studies will get us to...  
Next we will...  
This data will be used for...



# How are SBIR/STTR applications evaluated?



# BUDGET CONSIDERATIONS



*Technical Assistance Money – \$6,500 for Phase I; \$50,000 for Phase II*

SBIR guidelines:

- SBIR Phase I (  $\geq 66\%$  of the work at company)
- SBIR Phase II (  $\geq 50\%$  of the work at company)

STTR statutory requirement:

- STTR Phase I and Phase II ( $\geq 40\%$  at the company,  $\geq 30\%$  at research institution)

*Work may be outsourced to a subcontractor(s); fee-for-service activities may count as direct costs*

# 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>

**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 (2019-nCoV).

# THANK YOU

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## CONTACT INFO

NCI SBIR DEVELOPMENT CENTER

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

240.276.5300



# INVESTOR INITIATIVES PROGRAM

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## INVESTOR REVIEW//

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Current & recent awardees can apply (~100/year)

Reviewed by pharma/MedTech & venture partners (e.g., BMS, Eli Lilly, OrbiMed, RA Capital)

**ALL** applicants receive constructive reviewer feedback

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## FUNDING SUPPORT TO PITCH//

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NCI matches 25-30 companies with stage and technology appropriate events

Assists with presentation fees for one individual

NCI or Pharma managed company showcases

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## MENTORING & PITCH COACHING //

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Selected companies receive coaching, give pitches at investor forums and conferences, and meet one-on-one with investor attendees

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## DIRECT INTRODUCTION TO INVESTORS//

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Develop a wide network of investor/strategic partners

Companies are profiled in an investor-oriented booklet shared via newsletters and email

Direct introductions to SBIR awardees in NCI SBIR portfolio

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Investor Initiatives Mini-Review in *Clinical and Translational Science*: <https://bit.ly/3vfLTwB>

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# TRECS WORKSHOP

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## NCI SBIR Workshop on T ranslational R esources to E nhance C ommercialization S uccess

- Open to active awardees
- Speakers from FDA, CMS, NSF, pharma, med-tech, VCs and across NIH
- Panels on other sources of federal funding, resources & collaborative programs at NIH, and unique life science investment organizations
- 300+ One-on-one meetings with program directors and speakers
- Networking and Brainstorm sessions with other SBIR peers and NIH staff
- Next workshop – 2023



More information: <https://sbir.cancer.gov/programseducation/TRECS2021>

# PLAN WEBINAR SERIES

## Peer Learning and Networking (PLAN) Webinar Series

<https://sbir.cancer.gov/programseducation/plan>

### Topics:

- ❑ How to Write a Good Specific Aims Page
- ❑ Spotlight Video: Small Business Transition Grant (SBTG)
- ❑ Implementing a Quality Management System (QMS)
- ❑ Spotlight Video: Top Takeaways on How to Set Up a Small Business
- ❑ Keys to a Successful IND Submission
- ❑ Spotlight Video: CARE Success Stories



### Part I. Presentation

Watch pre-recorded panelist presentation on [the PLAN webpage](#) prior to joining the webinar and write down your questions.



### Part II. Panel Session

Attend real-time panel session and ask your questions to the panelist and/or the moderating NCI SBIR program director.

# EXECUTIVE ROUNDTABLE

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- Platform for founders/CEOs/other C-Level Executives of NCI SBIR-funded startups to mentor and advise each other on real-life startup issues.
- 3 cohorts ongoing
- 2-3 hours once every 2 months



- Applications open later in 2022
- Technology or indication focus



- Networking
- Ongoing Mentoring & Advice
- Potential Partnerships



- Currently virtual due to COVID-19



- C-Level Executives of all awardees
- 10-12 participants per cohort



# CONNECTING AWARDEES WITH REGULATORY EXPERTS (CARE)

*The CARE Program supports awardee interactions with FDA and encourages communication with regulators early on in the technology development process*

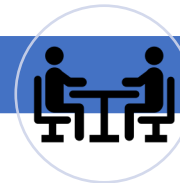
- Program to encourage early communication between small businesses and FDA
- New cohort in spring each year – stay tuned for 2023 application date!

## CARE Program



- Educational presentations with speakers from CBER, CDER, and CDRH
- Recordings available from Spring 2021 [FDA Workshop for Oncology Start-ups](#)
- Stay tuned for future workshops!

## Workshops



- <https://sbir.cancer.gov/resources/fda-resources>
- Resources webpage of key guidance documents applicable to small businesses
- Curated list of links to FDA educational webinars

## NCI SBIR Website

