

MARCH 30, 2021 | FDA ONCOLOGY WORKSHOP

# FEDERAL RESOURCES FOR ONCOLOGY START- UPS

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DEEPA NARAYANAN  
SBIR DEVELOPMENT CENTER  
NATIONAL CANCER INSTITUTE

**SBIR**  
DEVELOPMENT CENTER



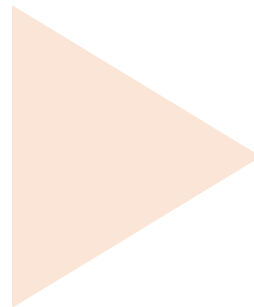
# SBIR/STTR PROGRAM

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## AMERICA'S LARGEST SEED FUND

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

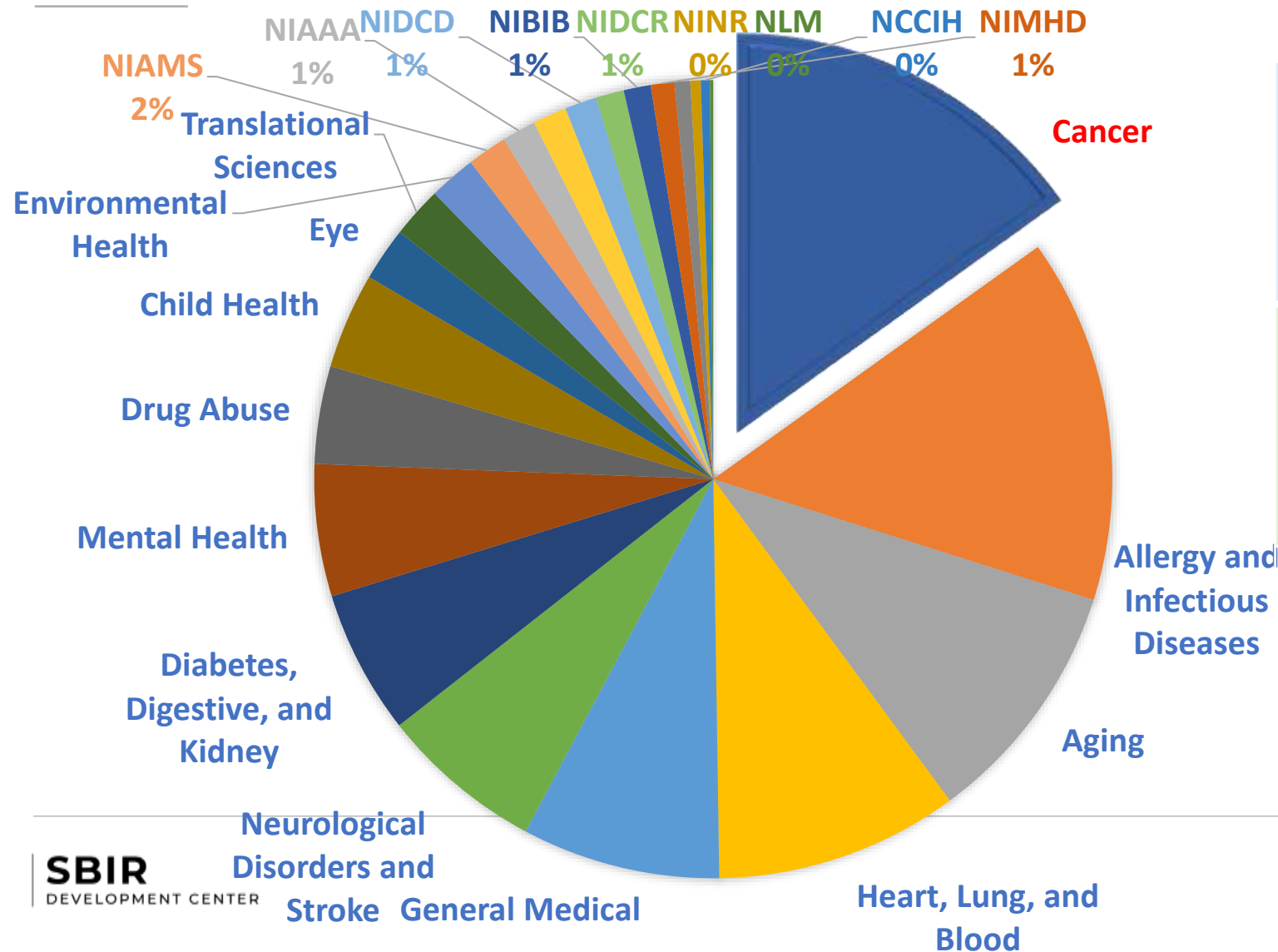
**NCI**  
**>450 projects**



**CBER/CDER/CDRH**

**FDA**

# ~\$180M/YEAR FOR CANCER SMALL BUSINESSES



Set Aside for FY20

## SBIR

SMALL BUSINESS  
INNOVATION  
RESEARCH

**\$157M (3.2%)**

## STTR

SMALL BUSINESS  
TECHNOLOGY  
TRANSFER

**\$22M (0.45%)**

**\$1.18B for NIH  
\$179M for NCI**

# NCI SBIR DEVELOPMENT CENTER

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## CENTRAL OVERSIGHT

Administer all 450+ 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

# 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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# 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

# TIP # 1

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**ARE YOU READY TO APPLY?**



# 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**)



# NCI SBIR PROGRAM STAFF

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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!



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



**Christie Canaria, PhD**  
*Program Director*  
Cancer/Biological Imaging, Research Tools, Devices, I-Corps at NIH



**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)



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



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



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



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



**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





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



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

# 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.
- <https://sbir.cancer.gov/aap>

 AAP PROVIDES	 AAP DOES <b>NOT</b> 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

# TIP # 2

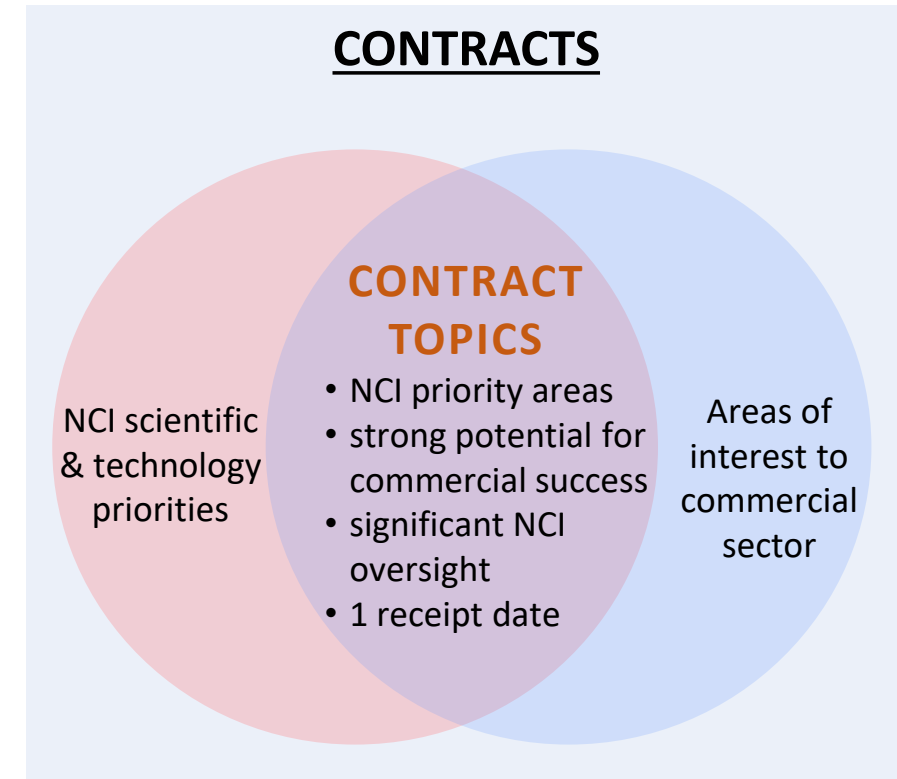
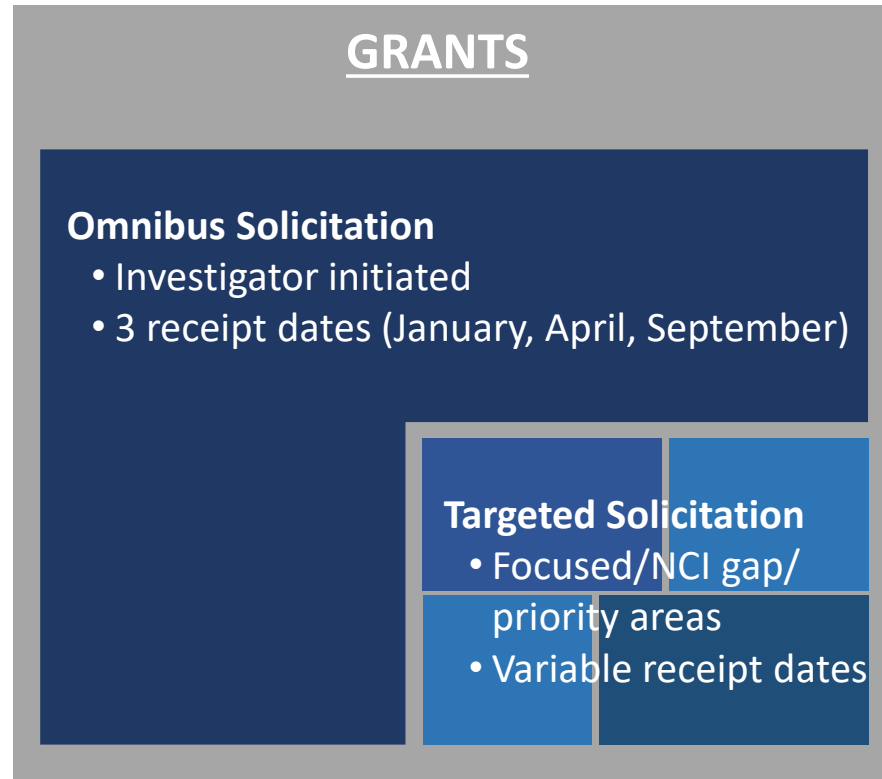
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## UNDERSTAND YOUR FUNDING OPPORTUNITY



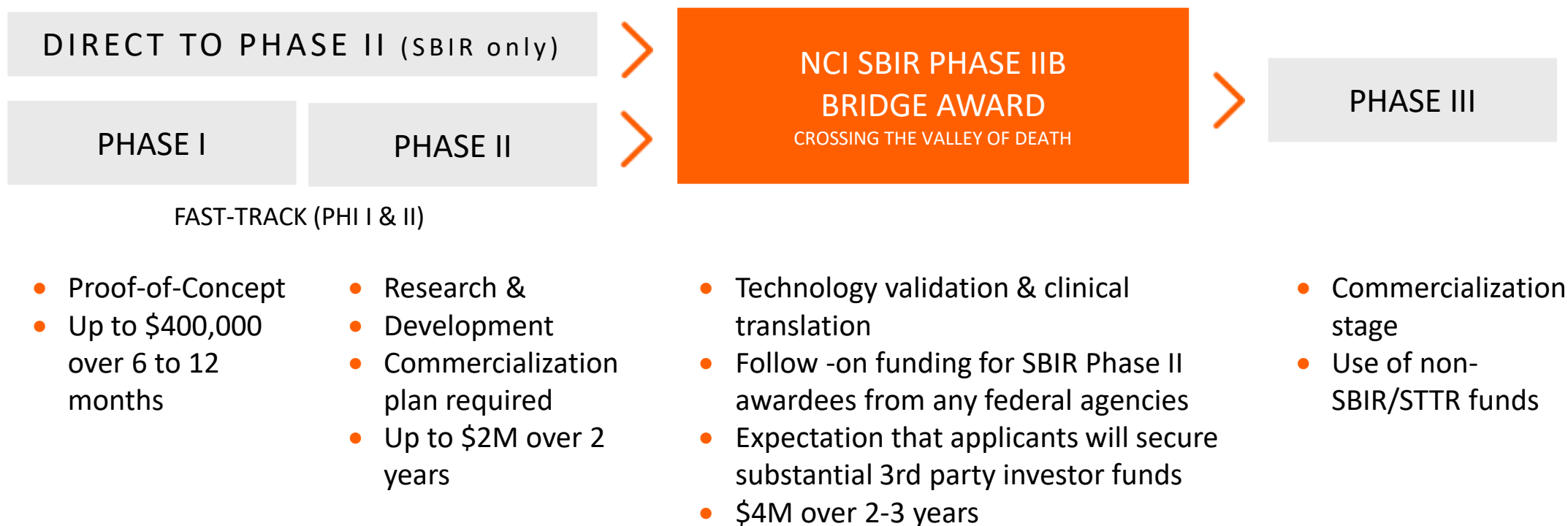
# FUNDING MECHANISMS

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# THREE-PHASE PROGRAM

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# 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		
Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings	PAR-18-801	PA-18-802	
SBIR IMAT (Innovative Molecular Analysis Technology) Development	PAR-18-303 (SBIR only)	No STTR	
Contract Solicitation	PHS 2020-1 (SBIR only)	No STTR	October
Phase IIB Bridge Award	RFA-CA-20-033	Same as SBIR	August 3, 2020

# OMNIBUS SOLICITATION

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

## 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!**

# NCI SBIR CONCEPT AWARD!

[https://sbir.cancer.gov/  
funding/concept](https://sbir.cancer.gov/funding/concept)



**WHITE PAPER:** March 26, 2021  
**PROPOSALS DUE:** July 23, 2021

- Looking for transformative technologies
- Phase I SBIR Contract Funding
- Technologies to address rare and pediatric cancer
- Fund experiments to obtain initial de-risking and proof-of-concept data.
- \$300K FOR one year of funding
- Focus is on Innovation
- improve cancer research, prevention, detection and care
- Preliminary data are not required.
- Submission of White Paper to get Program input

**Contact: Cherie Wells** [ncioasbir@mail.nih.gov](mailto:ncioasbir@mail.nih.gov)



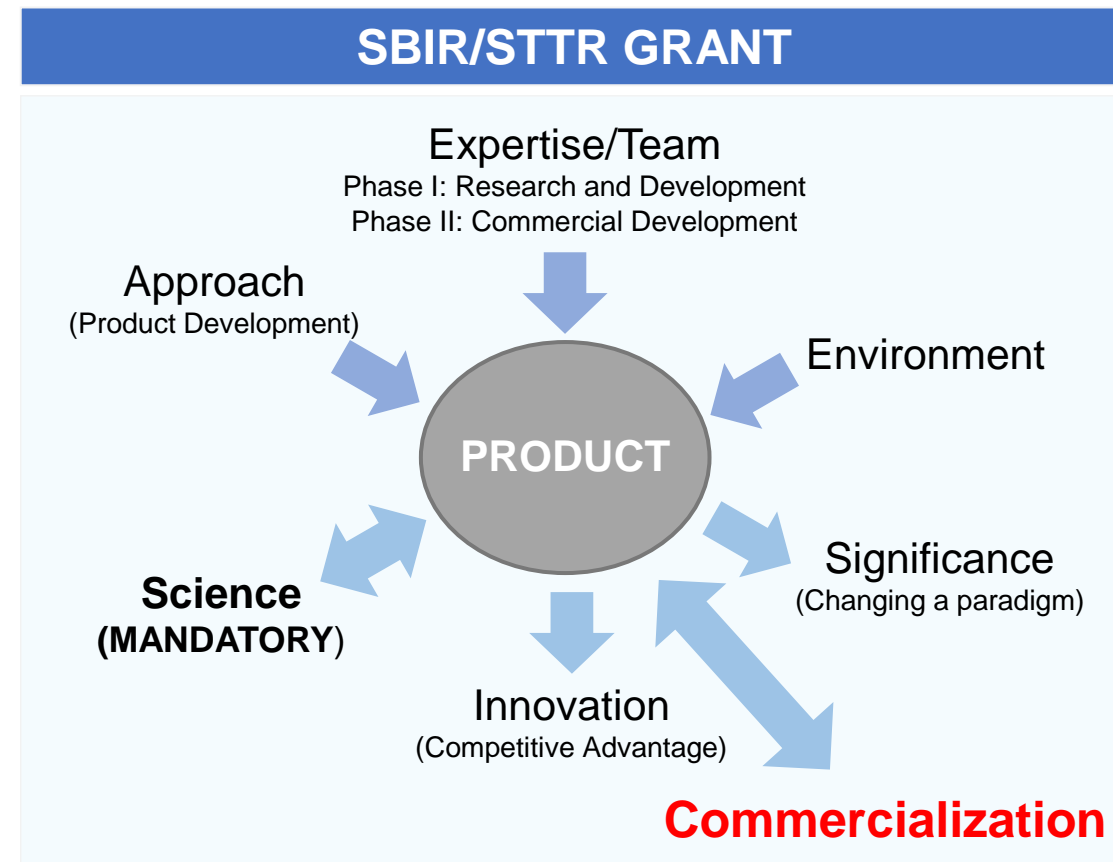
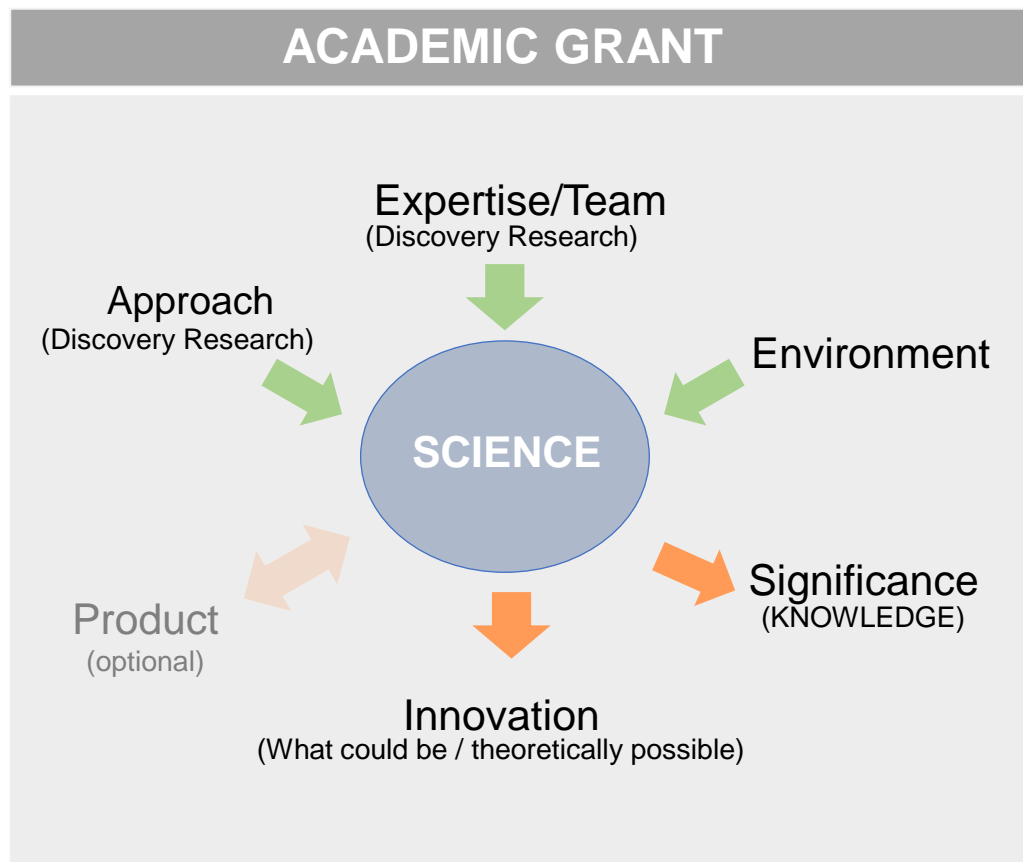
# TIP # 3

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## FOCUS ON YOUR PRODUCT



# TIP # 3: SBIR IS PRODUCT FOCUSSED



# TIP # 3: 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 the most up-to-date 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>
  - Look at sample applications, <https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44>

# TIP # 4

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## UNDERSTAND PEER REVIEW



# TIP #4: UNDERSTAND PEER REVIEW PROCESS



# TIP # 5

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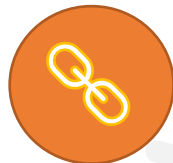
## TAKE ADVANTAGE OF THE PROGRAM



# 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.



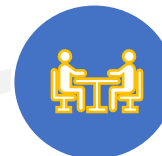
## CARE (REGULATORY PROGRAM)

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.



# Connecting Awardees with Regulatory Experts

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NCI SBIR supports awardee interactions with FDA and encourages communication with regulators early on in the technology development process

## CARE PROGRAM

- Pilot Program to encourage early communication between small businesses and FDA
- Participation from CDER, CDRH and CBER

## TRECS WORKSHOP

- Every two years
- Opportunity to meet 1:1 with regulators from FDA
- Educational panel presentations with speakers from FDA

## NCI SBIR WEBSITE

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



# INVESTOR INITIATIVES



# THANK YOU

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## CONTACT INFO

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