



# University Startups:

*How Can I Make the Most of Funding and Resources from the National Cancer Institute?*

1

## TODAY'S SPEAKERS

**Monique Pond, PhD**  
Program Director  
SBIR Development Center  
National Cancer Institute



- BS in Chemistry – UT Austin
- PhD in Chemistry – Penn State
- NRC Postdoc – National Institute of Standards & Technology (NIST)
- Regulatory Consultant – Whitsell Innovations

**Sanket Mishra, PhD**  
Co-founder of Grannus  
Therapeutics &  
Postdoctoral Fellow at  
University of Notre Dame



- B Pharmacy- University of Mumbai
- MS- Pharmaceutical Sciences- University of Mumbai
- MS and PhD in Medicinal Chemistry- The University of Kansas
- Postdoc fellow – University of Notre Dame

2

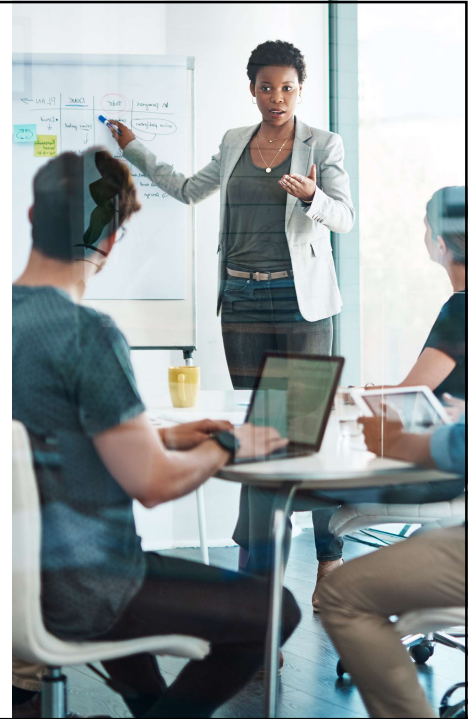
February 18, 2021 | AUTM Webinar

# NCI SBIR/STTR Funding & Resources

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**Monique Pond, PhD**  
PROGRAM DIRECTOR  
NATIONAL CANCER INSTITUTE

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3

## SBIR & STTR Overview

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4

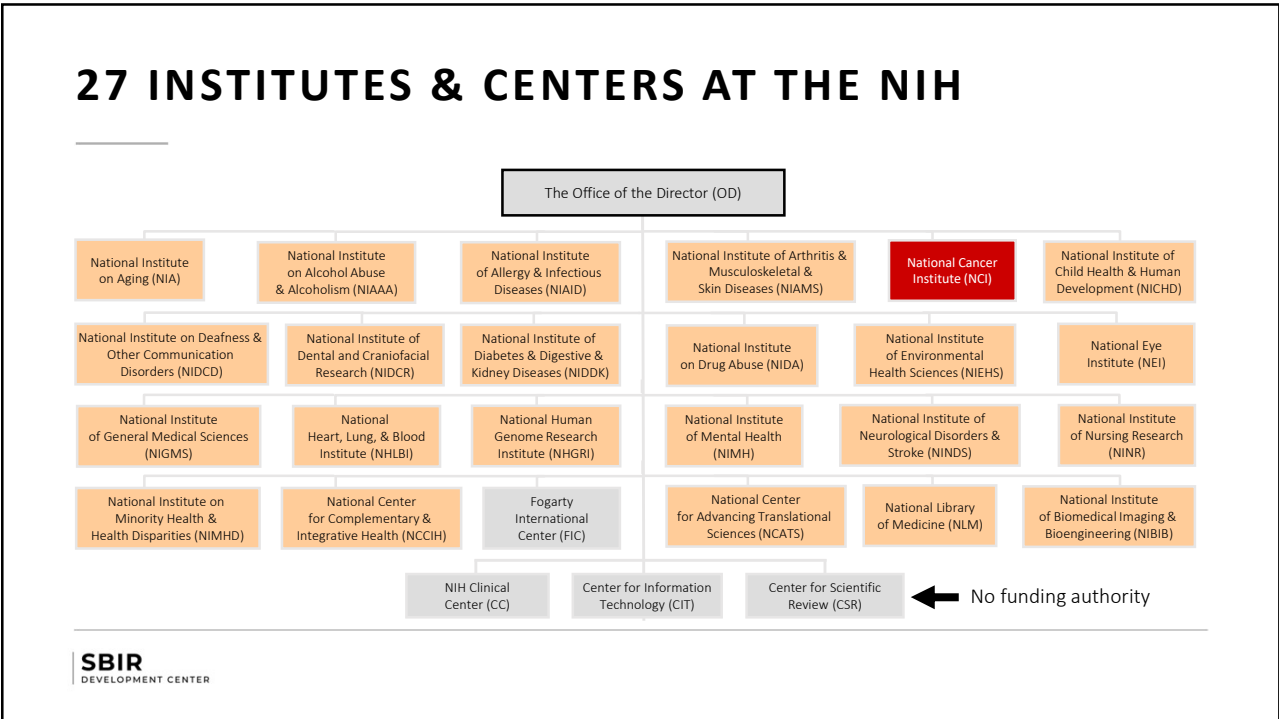
# SBIR PROGRAMS

## 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

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6

## CONGRESSIONALLY MANDATED PROGRAM

		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>

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7

## INTELLECTUAL PROPERTY (IP)

### Bayh-Dole Act – 1980

Permitted ownership of inventions made with support by federal funding:

- ✓ University
- ✓ Small business
- ✓ Non-profit institution



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8

## CRITICAL DIFFERENCES

SBIR		STTR
<b>Permits</b> research institution partners (e.g., universities)	PARTNERSHIP	<b>Requires</b> 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%) <b>MUST</b> be with the SBC for the duration of the project period	PI INVOLVMENT	PI primary employment not stipulated (min.10% effort to project)

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9

## ECONOMIC IMPACT



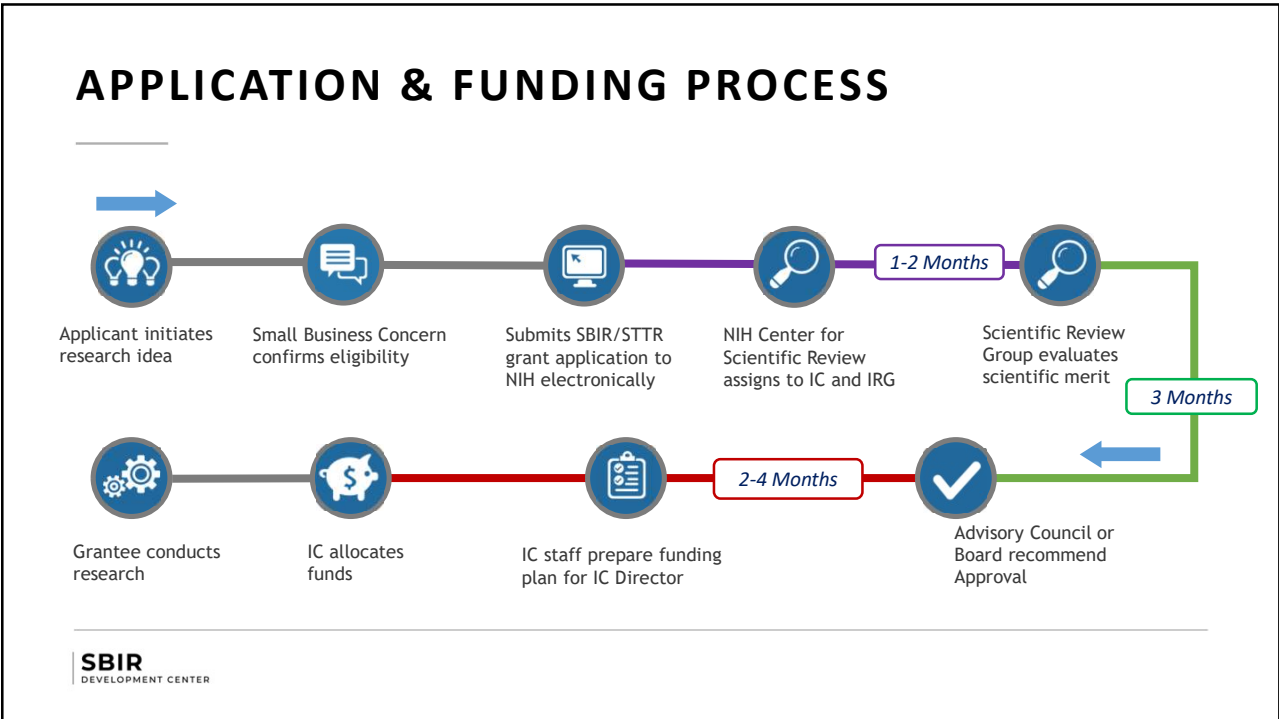
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10



# How does the funding process work?

11



12

# NIH EXTERNAL PEER REVIEW

## NIH peer review criteria

- ✓ Significance
- ✓ Investigator(s)
- ✓ Innovation
- ✓ Approach
- ✓ Environment

## Scientific Review Group

- Officer – NIH extramural staff scientist
- Reviewers – non-federal scientists
- Assign a score to each review criterion
- Overall impact score (if discussed)



# 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**)


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






## 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.

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## THREE-PHASE PROGRAM

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DIRECT TO PHASE II (SBIR Only)

PHASE I    PHASE II

FAST-TRACK (PHI I & II)

**NCI SBIR PHASE IIB  
BRIDGE AWARD**  
CROSSING THE VALLEY OF DEATH

PHASE III

- Proof-of-Concept
- **Up to \$400,000 over 9 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
- **\$4M over 2-3 years**

- Commercialization stage
- Use of non-SBIR/STTR funds

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18

# 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 April 5; January 5; September 5
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	
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 2021-1 (SBIR only)	No STTR	October 2021
Phase IIB Bridge Award	RFA-CA-20-033	Same as SBIR	August 2021

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19

# INNOVATIVE CONCEPT AWARD

**DUE DATES**

White Paper – March 26, 2021  
Proposals – July 23, 2021

**CONTACT**

Cherie Wells, SBIR Contracts Analyst  
Office of Acquisitions, NCI  
[ncioasbir@mail.nih.gov](mailto:ncioasbir@mail.nih.gov)

- **Eligibility**
  - Small Businesses working in rare and/or pediatric cancer technology
  - Must apply with a high-risk, high-reward potentially disruptive technology
- **Special Features**
  - Funding to de-risk idea and provide proof of concept for innovative and potentially transformative therapies, diagnostic tools, or preventive strategies focused on pediatric and/or rare cancers
  - Proposals DO NOT require preliminary data
  - Must identify an anticipated product
- **SBIR Contract**
  - Requirement for a White Paper so NCI can provide feedback before applying
  - Contract requirements will apply



Upcoming Webinar:  
Thursday, March 4, 2021  
2:00 pm ET

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20


# TRANSITION GRANT

**DUE DATES**

Letter of Intent – ASAP

Applications – March 10, 2021

- **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




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21

# SMALL BUSINESS TRANSITION GRANT



Phase I STTR	Transition	Phase II SBIR
<p><b>TRAINING</b></p> <ul style="list-style-type: none"> <li>• SBC PI: Postdoc</li> <li>• Mentoring plan required                             <ul style="list-style-type: none"> <li>• Technical mentor</li> <li>• Business mentor</li> </ul> </li> </ul> <p><b>TECHNICAL</b></p> <ul style="list-style-type: none"> <li>• PI preps technology to move to SBC</li> <li>• I-Corps at NIH required</li> </ul>	<p><b>PERSONNEL</b></p> <ul style="list-style-type: none"> <li>• PI moves to SBC</li> </ul> <p><b>TECH UPDATE</b></p> <ul style="list-style-type: none"> <li>• R&amp;D milestones</li> <li>• Commercialization plan</li> <li>• IP agreement</li> </ul>	<p><b>TRAINING</b></p> <ul style="list-style-type: none"> <li>• Same PI (non-transferrable)</li> <li>• Mentoring continues                             <ul style="list-style-type: none"> <li>• Contact type and frequency in mentoring plan</li> </ul> </li> </ul> <p><b>TECHNICAL</b></p> <ul style="list-style-type: none"> <li>• Most research conducted at SBC site</li> <li>• Small pivots allowed                             <ul style="list-style-type: none"> <li>• No major scope changes</li> </ul> </li> </ul>

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22



# Grannus Therapeutics

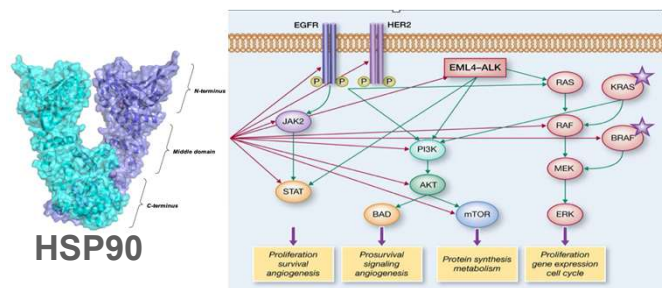
Sanket Mishra, PhD  
Co-founder of Grannus Therapeutics  
Postdoctoral Fellow at University of Notre Dame

23

## Technology & Background

HSP90: A molecular chaperone that regulates cellular proteins directly involved in tumor growth, proliferation, and survival

- ▶ 4 isoforms, Hsp90 $\alpha$ , Hsp90 $\beta$ , GRP94, & TRAP-1, 85% structurally identical
- ▶ Functionally involved in maturation, refolding, and aggregate regulation of client proteins
- ▶ HSP90 client proteins are involved in multiple signaling pathways associated with tumor growth, proliferation, and survival



*Major signaling kinases are clients of HSP90*

**Grannus**  
Therapeutics

24

## Technology Readiness for commercialization



OVER 4,500 PEER REVIEWED PUBLICATIONS



MORE THAN 17 MOLECULES INVESTIGATED

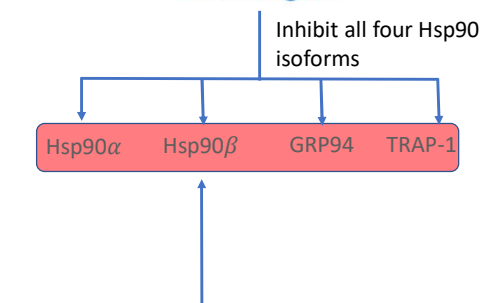


OVER 130 CLINICAL TRIALS FOCUSED ON HSP90 INHIBITION



PROGRAMS AT MAJOR PHARMA INCLUDING BMS, NOVARTIS, AND MERCK

**Previous molecules failed in Ph 2 /3 due to safety and dosing challenges**



Developed Compounds only bound Hsp90 $\beta$  Selectively and potently. Reducing the potential for adverse effects

**Grannus Therapeutics**

25

## Technology Readiness for commercialization

Hsp90 $\beta$ -selective inhibitors for the treatment of cancer

- Highly selective over other Hsp90 isoforms
- Potential to treat cancers without adverse effect (Ocular and Cardiotoxic)
- Lower dose may be required
- Breast, Colon and Leukemia

Studies required to identify a lead compound

- Medicinal chemistry to improve the Solubility and metabolism
- Preclinical studies involving in vitro/vivo DMPK and in vivo efficacy in cancer models

ARTICLE NATURE COMMUNICATIONS | (2018)9:425

DOI: 10.1038/s41467-017-02013-1 OPEN

Structure-guided design of an Hsp90 $\beta$  N-terminal isoform-selective inhibitor

Anuj Khandelwal<sup>1</sup>, Caitlin N. Kent<sup>2</sup>, Maurie Balch<sup>3</sup>, Shuxia Peng<sup>3</sup>, Sanket J. Mishra<sup>1</sup>, Junpeng Deng<sup>3</sup>, Victor W. Day<sup>4</sup>, Weiya Liu<sup>5</sup>, Chitra Subramanian<sup>6</sup>, Mark Cohen<sup>6</sup>, Jeffery M. Holzbeierlein<sup>5</sup>, Robert Matts<sup>3</sup> & Brian S.J. Blagg<sup>2</sup>

pubs.acs.org/jmc Article

**The Development of Hsp90 $\beta$ -Selective Inhibitors to Overcome Detriments Associated with pan-Hsp90 Inhibition**

Sanket J. Mishra, Weiya Liu, Kristin Beebe, Monimoy Banerjee, Caitlin N. Kent, Vitumbiko Munthali, John Koren, III, John A Taylor, III, Leonard M. Neckers, Jeffrey Holzbeierlein, and Brian S. J. Blagg<sup>®</sup>

Cite This: *J. Med. Chem.* 2021, 64, 1545–1557 Read Online Journal of Medicinal Chemistry

**Grannus Therapeutics**

26

## Company formation

### ○ Incorporation, LLC vs Corp

- Article of Organization
- Operating Agreement
- EIN

### ○ Registrations

- D&B (DUNS Number)
- SAM
  - DUNS and EIN required
  - MPIN
- SBA/SBIR
- Grants.gov (HHS SBIR)
- eRA Commons (HHS SBIR)



27

## Grant Submission

### ○ Writing

- Specific Aims
- Technology improvement  
(Late-stage medicinal chemistry)
- De-risking and validation  
(DMPK and in vivo studies )
- Focused experiments with Pragmatic deliverables
- Budget

### ○ Submission

- eRA Commons (ASSIST) or Grants.gov  
(Workspace)
- Consultants



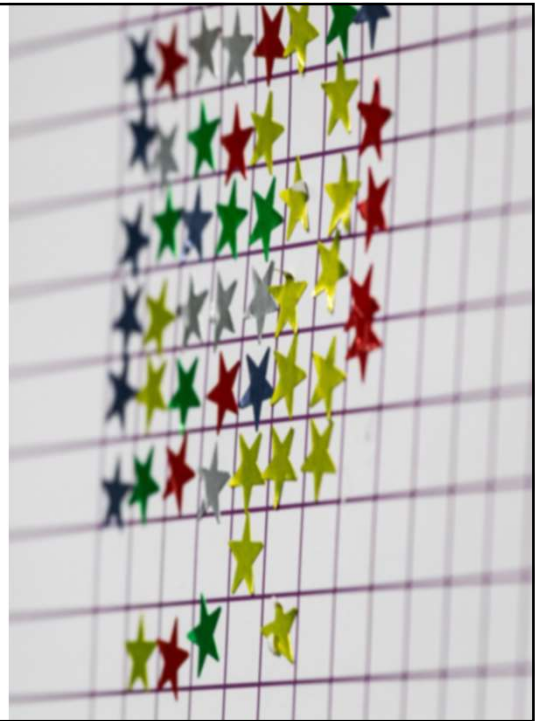
28

## Award

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### Organization Review

- Organizational chart
- Financial stability and statements
- Accounting and Office space lease
- Policy documents
- Funding agreement certification
- Interinstitutional Agreements



29

## Lab space

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### University Incubator space

- Shared Vs Own
- Meeting Safety requirements
- Maintaining MSDS for all the chemicals
- Equipment purchase



30

## Onboarding

- Business Executive (CEO)
- Board of Directors (BOD)
- Scientific Advisory Board (SAB)
- Employment contracts
  - Reflects the investment and compensation for all partners
  - Every 'What if' scenario defined

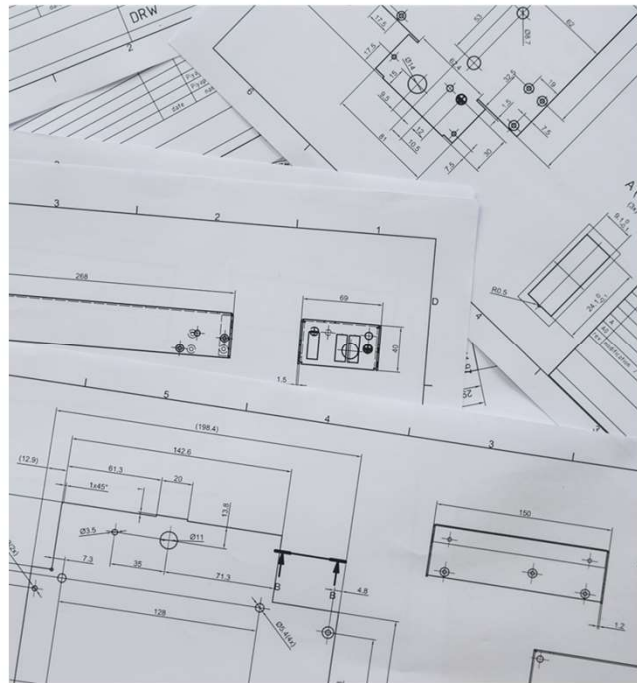


31

## License Acquisition

### License Term Sheet

- ✓ License Fees
- ✓ University Equity
- ✓ Royalty fees
- ✓ Sublicensing Fees
- ✓ Diligence
- ✓ Invention ownership
- ✓ Competing patents
- ✓ Interinstitutional Agreement  
if owned by >1 Universities




32






33


## GETTING STARTED

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**Read the solicitation & SF424 carefully to understand the requirements.**  
<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/sbir-sttr-forms-f.pdf>

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**Review similar, currently-funded NIH SBIR/STTR projects.**  
<https://projectreporter.nih.gov/reporter.cfm>

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**Look at some sample applications.**  
<https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44>

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34


## NCI SBIR Program Staff

Contact a Program Director!



**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



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




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




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




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




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



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



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




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



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



**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




35

## APPLICANT ASSISTANCE PROGRAM (AAP)

- AAP is FREE!
- Short, simple application
- For companies without previous NIH SBIR/STTR award
- IDEA states encouraged!

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

<div style="font-size: 2em; margin-bottom: 5px;">✓</div> <b>AAP PROVIDES</b>	<div style="font-size: 2em; margin-bottom: 5px;">✗</div> <b>AAP DOES NOT PROVIDE</b>
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



36

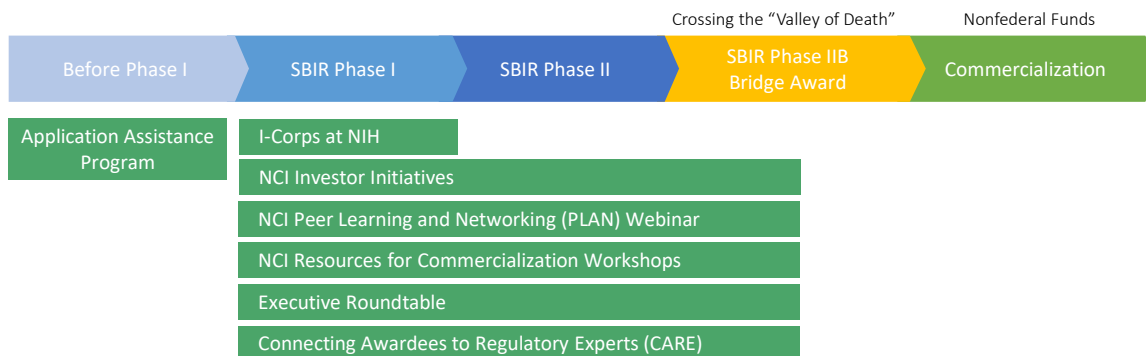


37



38

## NCI SBIR ASSISTANCE



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

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39

**I-CORPS**  
at  
**NIH**

### Funding Opportunity Announcement (FOA) [PA-19-029](#)

- 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
- 24 Institutes at NIH and CDC participate

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

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40

# INVESTOR INITIATIVES PROGRAM



## INVESTOR REVIEW//

Current and recent NCI awardees can apply (80-110 per year)

Reviewed by pharma and venture partners (e.g., Pfizer, J&J, GE, MPM Capital)

**ALL** applicants receive constructive feedback from investor reviewers



## FUNDING SUPPORT TO PITCH//

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

Assists with presentation fees for one individual

NCI or Pharma managed company showcases



## MENTORING & PITCH COACHING //

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

Industry mentoring



## DIRECT INTRODUCTION TO INVESTORS//

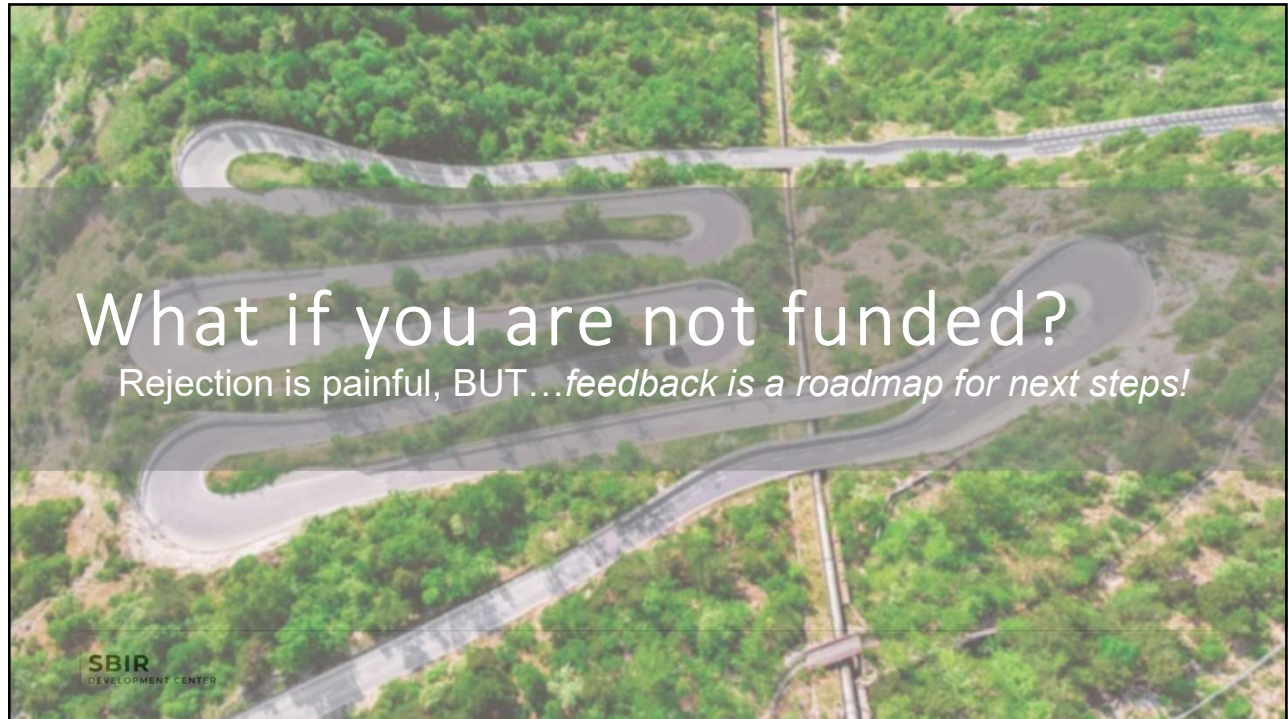
Develop a wide network of investor/strategic partners

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

Direct introductions to SBIR awardees in NCI SBIR portfolio



41



42

## COMMON PITFALLS - #1

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*What if the reviewers don't believe you are working on significant problem?*

- Consider reviewer comments from their point of view and their knowledge of current clinical practice (or relevant sector/customer segment)
- Address reviewer comments in an evidence-based fashion
- Be specific and quantitative when providing data to support your claims
- Obtain additional letters of support from stakeholders who can confirm the magnitude of the problem **AND** the potential impact of your solution

## COMMON PITFALLS - #2

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*What if the reviewers didn't understand your proposal?*

- **Possible Reason:** Proposal is not clearly written
  - **Solution:** Improve your presentation; check for spelling or grammatical errors, make sure figures are clearly labeled, etc.
- **Possible Reason:** Not enough data, or vague descriptions of the technology
  - **Solution:** Present key data in the application; reference publications to save space, but show the most important figures!

## COMMON PITFALLS - #3

*What if the reviewers believe your team is not well qualified?*

- Provide more background on your team members' qualifications
- Strengthen your team by adding collaborators and consultants
- Consider including a management plan/strategy that describes who is completing the work and how they are qualified
- Consider a multi-PI team



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45

## EVENTS

Learn about our funding opportunities and resources from NCI SBIR program directors!

- **NCI SBIR Monthly Office Hour**
  - 3rd Friday of each month
  - A great opportunity to connect one-on-one with an NCI SBIR program director
  - Sign up and send your 1-page technology summary to Bryce Geiling ([bryce.geiling@nih.gov](mailto:bryce.geiling@nih.gov)).
- **Upcoming Events**
  - Events are listed on NCI SBIR Events Page: <https://sbir.cancer.gov/newsevents/events>
  - Sign up for e-newsletter for the latest update: <https://sbir.cancer.gov/emailsignup>



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46



# Q & A

