JANUARY 26, 2021 | BIO PRESENTATION

NCI SBIR: FUNDING AND COMMERCIALIZATION RESOURCES FOR CANCER TECHNOLOGIES

MICHAEL WEINGARTEN
NANCY KAMEI
SBIR DEVELOPMENT CENTER
NATIONAL CANCER INSTITUTE
TODAY’S SPEAKERS

Michael Weingarten
Director
SBIR Development Center
National Cancer Institute

Nancy Kamei
Program Director
SBIR Development Center
National Cancer Institute
ABOUT SBIR & STTR
CONGRESSIONALLY MANDATED PROGRAM

<table>
<thead>
<tr>
<th>Program</th>
<th>Description</th>
<th>Agencies Requirement</th>
<th>Set Aside for FY20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SBIR</strong></td>
<td>Set-aside program for small business concerns to engage in Federal R&amp;D with the potential for commercialization</td>
<td>Federal agencies with an extramural R&amp;D budget &gt; $100M</td>
<td>$157M (3.2%)</td>
</tr>
<tr>
<td><strong>STTR</strong></td>
<td>Set-aside program to facilitate cooperative R&amp;D between small business concerns and U.S. research institutions with the potential for commercialization</td>
<td>Federal agencies with an extramural R&amp;D budget &gt; $1B</td>
<td>$22M (0.45%)</td>
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<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>$1.18B for NIH</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>$179M for NCI</td>
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</table>
27 INSTITUTES & CENTERS AT THE NIH

The Office of the Director (OD)

- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse & Alcoholism (NIAAA)
- National Institute of Allergy & Infectious Diseases (NIAID)
- National Institute of Arthritis & Musculoskeletal & Skin Diseases (NIAMS)
- National Cancer Institute (NCI)
- National Institute of Child Health & Human Development (NICHD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)
- National Institute of Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of General Medical Sciences (NIGMS)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders & Stroke (NINDS)
- National Institute of Nursing Research (NINR)
- National Institute of Biomedical Imaging & Bioengineering (NIBIB)
- National Institute on Minority Health & Health Disparities (NIMHD)
- National Heart, Lung, & Blood Institute (NHLBI)
- National Human Genome Research Institute (NHGRI)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders & Stroke (NINDS)
- National Library of Medicine (NLM)
- National Institute of Biomedical Imaging & Bioengineering (NIBIB)
- Fogarty International Center (FIC)
- National Center for Advancing Translational Sciences (NCATS)
- National Center for Complementary & Integrative Health (NCCIH)
- National Library of Medicine (NLM)
- NIH Clinical Center (CC)
- Center for Information Technology (CIT)
- Center for Scientific Review (CSR)

No funding authority
### NCI SBIR Core Activities

<table>
<thead>
<tr>
<th>Central Oversight</th>
<th>Guidance</th>
<th>Outreach</th>
<th>Funding</th>
<th>Networking</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administer all 400+ SBIR/STTR awards at the NCI</td>
<td>Help prepare for application, resubmission, &amp; discuss funding options</td>
<td>Attend conferences/workshops &amp; visit organizations/universities to raise awareness of the program</td>
<td>Seed emerging technology areas through targeted grant &amp; contract funding opportunities</td>
<td>Maintain a network of investors and facilitate connections between portfolio companies &amp; investors/strategic partners</td>
<td>Provide entrepreneurship training on key topics such as IP, regulatory strategy, &amp; how to build a strong team</td>
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</tbody>
</table>
REACH OUT TO AN NCI SBIR PROGRAM DIRECTOR

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
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.
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)
## CRITICAL DIFFERENCES

<table>
<thead>
<tr>
<th>SBIR</th>
<th>STTR</th>
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<tbody>
<tr>
<td><strong>Permits</strong></td>
<td><strong>Requires</strong></td>
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<tr>
<td><strong>P</strong>artnership</td>
<td><strong>P</strong>artnership</td>
</tr>
<tr>
<td>Small business may outsource ~33% of Phase I activities and 50% of Phase II activities</td>
<td>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)</td>
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<td><strong>D</strong>ivision of Labor</td>
<td><strong>D</strong>ivision of Labor</td>
</tr>
<tr>
<td>The PD/PI’s primary employment (i.e., &gt;50%) MUST be with the SBC for the duration of the project period</td>
<td>PI primary employment not stipulated (min.10% effort to project)</td>
</tr>
<tr>
<td><strong>P</strong>i Involvement</td>
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The award is ALWAYS made to the small business concern.
FUNDING MECHANISMS

**GRANTS**

**Omnibus Solicitation**
- Investigator initiated
- 3 receipt dates (January, April, September)

**Targeted Solicitation**
- Focused/NCI gap/priority areas
- Variable receipt dates

**CONTRACTS**

**CONTRACT TOPICS**
- NCI priority areas
- Strong potential for commercial success
- Significant NCI oversight
- 1 receipt date

Areas of interest to commercial sector

NCI scientific & technology priorities
THREE-PHASE PROGRAM

DIRECT TO PHASE II (SBIR Only)

PHASE I

PHASE II

FAST-TRACK (PHI I & II)

• Proof-of-Concept
• Up to $400,000 over 6 to 12 months

• Research & Development
• Commercialization plan required
• Up to $2M over 2 years

NCI SBIR PHASE IIB BRIDGE AWARD
CROSSING THE VALLEY OF DEATH

PHASE III

• 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
SUCCESS STORY: ONCOIMMUNE

2016
OncoImmune received SBIR award to fund the early-stage development of CD24Fc.

2020
OncoImmune received funding, including a $1M supplement award from NCI SBIR, for clinical trial of CD24Fc to treat COVID-19.

November 2020
Merck announced the acquisition of OncoImmune for $425 million.

December 2020
HHS and DoD to collaborate with Merck to continue development of the COVID-19 treatment

COLLABORATE WITH NCI SBIR

• Information sessions for your constituents
  – Outreach events with NCI SBIR program director
  – 1:1 sessions with NCI SBIR program director

• Success stories featuring small business from your state
  – Share the success of NCI SBIR-funded small businesses on NCI SBIR channels
    • Website, Twitter, LinkedIn, and partner channels
FUNDING OPPORTUNITIES AT NCI
<table>
<thead>
<tr>
<th>TITLE</th>
<th>SBIR FOA</th>
<th>STTR FOA</th>
<th>RECEIPT DATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omnibus Solicitation</td>
<td>PA-20-260 (General)</td>
<td>PA-20-265 (General)</td>
<td>Standard Receipt Dates</td>
</tr>
<tr>
<td></td>
<td>PA-20-262 (Clinical Trial)</td>
<td>PA-20-261 (Clinical Trial)</td>
<td>September 5; January 5; April 5</td>
</tr>
<tr>
<td>SBIR Technology Transfer (technology transfer out of NIH intramural labs)</td>
<td>PA-18-705 (SBIR only)</td>
<td>No STTR</td>
<td>~ October 2021</td>
</tr>
<tr>
<td>Illuminating the Druggable Genome (IDG)</td>
<td>PA-19-034</td>
<td>PA-19-033</td>
<td>~ August 2021</td>
</tr>
<tr>
<td>Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings</td>
<td>PAR-18-801</td>
<td>PA-18-802</td>
<td></td>
</tr>
<tr>
<td>SBIR IMAT (Innovative Molecular Analysis Technology) Development</td>
<td>PAR-18-303 (SBIR only)</td>
<td>No STTR</td>
<td></td>
</tr>
<tr>
<td>Contract Solicitation</td>
<td>PHS 2022-1 (SBIR only; TBA)</td>
<td>No STTR</td>
<td></td>
</tr>
<tr>
<td>Phase IIB Bridge Award</td>
<td>RFA-CA-21-XXX (TBA)</td>
<td>Same as SBIR</td>
<td></td>
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SMALL BUSINESS TRANSITION GRANT
RFA-CA-21-001 - Small Business Transition Grant

An Entrepreneurial Training Grant Modeled After the K99/R00

Grad/Med Student
T32, R25, F30 (med)

Postdoctoral
T32, R25

Entrepreneur Path

Academic Investigator Path

Junior Faculty
F32, K01, K25, K22

Tenured Faculty
R01, K24

Small Biz Transition Grant

Entrepreneur
R41/R42, R43/R44
CONCEPT: SMALL BUSINESS TRANSITION GRANT

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

**Phase II SBIR**
- Permits collaboration with university
- PI primary employment MUST be with the SBC for the duration of the project period
- $2M / 2yrs (NCI)
CONCEPT: SMALL BUSINESS TRANSITION GRANT

**Phase I STTR**

**TRAINING**
- SBC PI: Postdoc
- Mentoring plan required
  - Technical Mentor
  - Business mentor

**TECHNICAL**
- PI preps technology to move to SBC
- I-Corps at NIH required

**Transition**

**PERSONNEL**
- PI moves to SBC

**TECH UPDATE**
- R&D Milestones
- Commercialization plan
- IP agreement

**Phase II SBIR**

**TRAINING**
- Same PI (non-transferrable)
- Mentoring Continues
  - Contact type and frequency in mentoring plan

**TECHNICAL**
- Most research conducted at SBC site
- Small pivots allowed
  - No major scope changes
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

National Cancer Institute
Kory Hallett, PhD
Kory.Hallett@nih.gov

National Human Genome Research Institute
Heidi Sofia, MPH, PhD
Heidi.sofia@nih.gov
SMALL BUSINESS CONCEPT AWARD
ICYMI: The new NCI #SBIR Concept Award NCI SBIR is now accepting applications. If your #SmallBiz is carving a path to significantly improve cancer research, prevention, detection and care in pediatric and/or rare cancers, we encourage you to learn more: go.usa.gov/x76fX
FUNDING DISRUPTIVE INNOVATION

Goal
• Support high-risk/high-reward technologies in pediatric/rare cancers
• De-risk disruptive innovation.
• Contract; not a Grant

Special Features
• Submission of White Paper to get Program input
• Short applications (15 pages v/s 50)
• Preliminary data are not required.
• Special Review Criteria
• Make awards rapidly (within six months)

Support
• Leverage NIH I-Corps Program
• Followed by another Phase I, Direct to Phase II or Fast-Track

RELEASED: NOVEMBER 20, 2020
PROPOSALS DUE: JULY 23, 2021
AWARDS EXPECTED: JANUARY 2022
WHAT IS INNOVATIVE?

What is innovative?

- Development of ground-breaking new products, technologies or tools
- Disruptive innovation rather than incremental innovation
- Transformative technologies with the potential to change clinical care

What is NOT innovative?

- Therapeutics targeting known pathways with FDA-approved agents
- Technologies in clinical stage or already far down the development pathway
- Continuation of already funded SBIR/STTR projects
PLEASE READ THE SOLICITATION

PURPOSE
Support small businesses developing highly innovative and transformative technologies that have the potential to create new scientific paradigms, establish entirely new and improved clinical approaches to significantly improve cancer research, prevention, detection and care for pediatric or rare cancers.

POINT OF CONTACT
Cherie Wells
SBIR Contract Analyst
NCI Office of Acquisitions
Phone: (240) 276-7255
E-mail: ncioasbir@mail.nih.gov

FOA
• Phase I only, clinical trials not allowed
• Only one receipt date
• Submit White Paper

BUDGET
• $300K total costs
• 1 year award

ELIGIBILITY
• Must be a small business
• At least 66% of the work must be done by the small business
• Encourage all offerors
NCI SBIR INITIATIVES AND RESOURCES
NCI SBIR ASSISTANCE

Before Phase I
- Application Assistance Program

SBIR Phase I
- I-Corps at NIH

SBIR Phase II
- NCI Investor Initiatives
- NCI Peer Learning and Networking (PLAN) Webinar
- NCI Resources for Commercialization Workshops
- CEO Roundtable
- Connecting Awardees to Regulatory Experts (CARE)

SBIR Phase IIB Bridge Award

Crossing the “Valley of Death”

Commercialization
- Nonfederal Funds

https://sbir.cancer.gov/resources
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](https://sbir.cancer.gov/aap)

### AAP PROVIDES

- Phase I SBIR/STTR application preparation support and review
- Specific Aims page review and advice
- Submission process coaching

### AAP DOES NOT PROVIDE

- Grant writer
- Research plan development
- Small business registration or NIH application submission services
NCI SBIR Workshop on **Translational Resources to Enhance Commercialization Success**

Next Date: March 2021

- 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
- Over 300 One-on-one meetings with program directors and speakers
- Networking and Brainstorm sessions with other SBIR peers and NIH staff

Peer Learning and Networking (PLAN) Webinar Series

- Series Goals:
  - Facilitate and encourage peer learning
  - Provide networking opportunities to NCI-funded entrepreneurs

- Format: 2 - 4 presenting companies share their experience and expertise and discuss potential areas of collaborations

- 2 - 4 webinars per year

- More topics to be added. Open to suggestions!

https://sbir.cancer.gov/programseducation/plan
Current and recent NCI SBIR/STTR awardees can apply (80-110 per year) 

ALL applicants receive constructive feedback from investor reviewers 

Feedback strengthens development efforts and future investor outreach 

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

Selected companies are profiled in an investor-oriented booklet 

Each year, several investors ask for direct introductions to SBIR awardees based on their profile in the investor booklet (e.g., 15 introductions in 2017)
INVESTOR INITIATIVES 2018-2019

36 Companies
10 Showcases
470+ Meetings with investors & strategic partners

Each company selected to present received pitch-coaching from SBIR staff and/or external investors which added significant value to the presenters.

97% said “Investor Initiatives helped us progress toward our goals”
92% said “The value of the event was mostly to extremely valuable”
INVESTOR INITIATIVES 2017

- 69% of the selected awardees in 2016 are either still in discussions or already completed an investment or partnership and half of those specifically credited NCI’s contribution to the deal.

(NCI SBIR collects both short-term and long-term feedback from selected companies as the time from presentation to a secured deal is often 18 months or longer)

ONTARGET LABORATORIES

Investor Initiatives 2016

- Presented at J&J-organized showcase of NCI SBIR awardees
- Secured $40 million in funding from J&J’s venture arm.
- Met with J&J’s venture arm at the showcase & recently announced the major investment.

CellSight Technologies

Investor Initiatives 2017

- Secured a collaboration partnership/investment from Boehringer Ingelheim at a showcase presentation supported by NCI through Investor that is funding a clinical trial of the SBIR-funded technology

JBS SCIENCE

Investor Initiatives 2016

- Met with an investment firm at two industry showcases through participation in Investor Initiatives which culminated in an agreement for a collaboration and validation study funded by the external investment.
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
I-CORPS AT NIH CASE STUDY

Laparoscopic image fusion box that works with a surgeon’s existing lap camera and ultrasound.

<table>
<thead>
<tr>
<th>Before I-Corps</th>
<th>IGI Technologies at I-Corps</th>
<th>After I-Corps</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Thought all surgeons would want to incorporate ultrasound into their laparoscopic surgeries</td>
<td>• Dec 2014 – IGI Technologies completes I-Corps at NIH</td>
<td>• 2015 Went through NIH CAP program</td>
</tr>
<tr>
<td>I-Corps at NIH Learnings &amp; Pivot</td>
<td>• Thoracic surgeons “would do anything to localize tumors minimally invasively”</td>
<td>• Jun 2015 – Published technical paper in peer-reviewed journal, Academic Radiology</td>
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<tr>
<td></td>
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<td>• Mar 2017 – Received Phase II STTR grant</td>
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**EXECUTIVE ROUND TABLE**

- Platform for founders/CEOs/other C-Level Executives of NCI SBIR-funded startups to mentor and advise each other on real-life startup issues.
- 2 pilot cohorts already ongoing
- 2-3 hours once every 1-2 months

<table>
<thead>
<tr>
<th>Applications open Summer 2020</th>
<th>Networking</th>
<th>In person or Virtual</th>
<th>C-Level Executives of all awardees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohorts begin Fall 2020</td>
<td>Ongoing Mentoring &amp; Advice</td>
<td>Potential Partnerships</td>
<td>10-12 participants per cohort</td>
</tr>
</tbody>
</table>
Connecting Awardees with Regulatory Experts

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

**CARE PROGRAM**
- Cohort 1: May - Oct 2019
- Pilot Program to encourage early communication between small businesses and CDRH
- Stay tuned for future cohorts

**TRECS WORKSHOP**
- Spring 2021
- Opportunity to meet 1:1 with regulators from FDA
- Educational panel presentations with speakers from FDA

**NCI SBIR WEBSITE**
- Coming soon!
- Resources webpage of key guidance documents applicable to small businesses
- Curated list of links to FDA educational webinars

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SBIR DEVELOPMENT CENTER
### Keys to a Strong SBIR Application

- Innovative Product Focused Science
- Demonstrated Clinical/Market Need & Commercial Potential
- Understanding the Review Criteria
- Projects Should Involve Appropriate Collaborators
- Well Written Applications that Follows the Submission Guidelines
- Review Sample Applications & other Funded Projects
- Submit Early

**Contact NCI SBIR Program Before Applying**
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  
THANK YOU

CONTACT INFO
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