NCI SBIR & STTR: Advancing the Commercialization of New Cancer Innovations

CHRISTIE CANARIA AND NANCY KAMEI
PROGRAM DIRECTORS
NATIONAL CANCER INSTITUTE
SPEAKERS

Christie Canaria

Nancy Kamei
ABOUT
SBIR & STTR
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
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 Arthritis & Musculoskeletal & Skin Diseases (NIAMS)
- National Cancer Institute (NCI)
- National Institute on Aging (NIA)
- National Institute of Arthritis & Musculoskeletal & Skin Diseases (NIAMS)
- National Institute of Allergy & Infectious Diseases (NIAID)
- National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of General Medical Sciences (NIGMS)
- National Library of Medicine (NLM)
- National Institute of Nursing Research (NINR)
- National Institute of Biomedical Imaging & Bioengineering (NIBIB)
- National Institute of Minority Health & Health Disparities (NIMHD)
- 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 Institute of Biomedical Imaging & Bioengineering (NIBIB)
- Fogarty International Center (FIC)
- National Center for Advancing Translational Sciences (NCATS)
- National Library of Medicine (NLM)
- National Institute of Biomedical Imaging & Bioengineering (NIBIB)
- NIH Clinical Center (CC)
- National Library of Medicine (NLM)
- National Institute of Biomedical Imaging & Bioengineering (NIBIB)
- Center for Information Technology (CIT)
- National Institute of Biomedical Imaging & Bioengineering (NIBIB)
- Center for Scientific Review (CSR)

No funding authority
### CONGRESSIONALLY MANDATED PROGRAM

<table>
<thead>
<tr>
<th>SBIR</th>
<th>Set-aside program for small business concerns to engage in Federal R&amp;D with the potential for commercialization</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMALL BUSINESS INNOVATION</td>
<td>Federal agencies with an extramural R&amp;D budget &gt; $100M</td>
</tr>
<tr>
<td>RESEARCH</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>STTR</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>
</tr>
<tr>
<td>SMALL BUSINESS TECHNOLOGY</td>
<td>Federal agencies with an extramural R&amp;D budget &gt; $1B</td>
</tr>
<tr>
<td>TRANSFER</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Set Aside for FY20</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBIR</td>
<td>$157M (3.2%)</td>
</tr>
<tr>
<td>STTR</td>
<td>$22M (0.45%)</td>
</tr>
</tbody>
</table>

Total: $1.18B for NIH $179M for NCI
THREE-PHASE PROGRAM

DIRECT TO PHASE II

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

• 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

NCI SBIR PHASE IIB BRIDGE AWARD CROSSING THE VALLEY OF DEATH

PHASE III

• Commercialization stage
• Use of non-SBIR/STTR funds
## BUDGET LIMITS

<table>
<thead>
<tr>
<th></th>
<th>Standard Award</th>
<th>Hard Cap</th>
<th>Waiver Cap*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>$150,000</td>
<td>$252,131</td>
<td>NCI: $400,000</td>
</tr>
<tr>
<td>Phase II</td>
<td>$1.0M</td>
<td>~$1.68M</td>
<td>NCI: $2.0M</td>
</tr>
</tbody>
</table>

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


ELIGIBILITY

1. Applicant must be a Small Business Concern (SBC)

2. Organized for-profit U.S. business (based in the U.S. and work performed in the U.S.)

3. 500 or fewer employees, including affiliates

4. > 50% U.S.-owned by individuals and independently operated
   OR
   > 50% owned and controlled by another (one) business concern that is > 50% owned and 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.
## CRITICAL DIFFERENCES

<table>
<thead>
<tr>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Permits</strong> research institution partners (e.g., universities)**</td>
<td><strong>Requires</strong> research institution partners (e.g., universities)**</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>
</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>
</tbody>
</table>
FAQs FROM INSTITUTION RESEARCHERS
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.
If I'm employed by a university and own a small business, do I need two distinct eRA Commons names for each entity?

A PI does not need two distinct eRA Commons names for each entity. An individual only needs one eRA Commons PI account, which will follow them throughout their career. A PI may have multiple affiliations with a university and a small business. However, a small business official at the small business concern must have a separate organizational eRA Commons account for the small business.
WHEN TO FORMALIZE THE COMPANY

Do we have to be a formal company before we apply for a SBIR/STTR?

The grants.gov submission/registration process requires that an applicant be a formal entity in order to submit an application to the federal government. However applicants need not meet the SBIR and STTR eligibility requirements until the time of award.
MULTIPLE PIs

May multiple PD/PIs be included on SBIR and STTR applications?

Yes, more than one PD/PI, or multiple PDs/PIs, may be designated on the application for projects that require a “team science” approach that clearly does not fit the single-PD/PI model. Each PD/PI must have a PD/PI role and a leadership plan is required. All PDs/PIs must be registered in the NIH eRA Commons prior to the submission of the application. The decision of whether to apply for a single PD/PI or multiple PD/PI grant is the responsibility of the investigators and applicant organizations and should be determined by the scientific goals of the project. Please also refer to the SF424 SBIR/STTR (R&R) Application Guide for more information about the requirements for multiple PD/PIs.
Does the NIH Early Stage Investigator Policy apply to SBIR/STTR awards?

No, the advantages of Early State Investigator (ESI) status apply only to applicants for traditional NIH research grants (R01s) and NIH Director’s New Innovator Grants (DP2s). More information about the ESI status can be found on the NIH New and Early Stage Investigator (ESI) Policies page.
INTELLECTUAL PROPERTY

Does my small business need intellectual property agreements as part of my SBIR/STTR grant application?

A primary goal of the SBIR/STTR programs is the commercialization of technologies under the SBIR/STTR award. When accepting monies under an SBIR/STTR award, the small business is certifying that it is able to conduct the funded research toward commercialization. Therefore, a small business should ensure its ability to achieve that goal under its grant application and to freely move forward with the research. For example, under an STTR award which requires collaboration between a small business and a nonprofit research institution, it is expected that intellectual property issues between the partners that should be addressed early on to ensure that the flow of the research, development, and commercialization of the project continues unimpeded. Accordingly, small businesses and nonprofit research institutions should consider using the "Model STTR Intellectual Property Agreement" to address the allocation of rights in intellectual property and rights to carry out follow-on research, development, or commercialization. While IP agreements/arrangements should be worked out to ensure what the small business is proposing in its SBIR/STTR grant application will be achievable, these need not be submitted as part of the grant application.

https://sbir.nih.gov/sites/default/files/STTRModelAgreement.doc
APPLICATION & FUNDING PROCESS

Applicant initiates research idea
Small Business Concern confirms eligibility
Submits SBIR/STTR grant application to NIH electronically
nih Center for Scientific Review assigns to IC and IRG
Scientific Review Group evaluates scientific merit

1-2 Months

1-2 Months

3 Months

2-4 Months

Grantee conducts research
IC allocates funds
IC staff prepare funding plan for IC Director
Advisory Council or Board recommend Approval

SBIR DEVELOPMENT CENTER
SUCCESS RATES

Applications reviewed vs. applications awarded

<table>
<thead>
<tr>
<th>Phase</th>
<th>Applications Reviewed</th>
<th>Applications Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>778</td>
<td>4,672</td>
</tr>
<tr>
<td>Phase II</td>
<td>454</td>
<td>158</td>
</tr>
<tr>
<td>NCI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>1,087</td>
<td>139</td>
</tr>
<tr>
<td>Phase II</td>
<td>68</td>
<td>23</td>
</tr>
</tbody>
</table>
NCI SBIR Development Center Offers a wide range of funding opportunities and commercialization resources.
NCI SBIR/STTR PORTFOLIO (n=475)

- $173M in FY19 for SBIR/STTR awards
- 86% Grants, 14% Contracts
## NCI SBIR CORE ACTIVITIES

<table>
<thead>
<tr>
<th>CENTRAL OVERSIGHT</th>
<th>GUIDANCE</th>
<th>OUTREACH</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>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FUNDING</th>
<th>NETWORKING</th>
<th>TRAINING</th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tr>
</tbody>
</table>
ECONOMIC IMPACT

$9.1 BILLION
in total sales to date of products and services resulting from the NCI SBIR/STTR Phase II awards

$26.1 BILLION
in total economic output nationwide

368 awards with sales, royalties, and follow-on R&D funding

$2.9 BILLION
in new tax revenues (federal, state, and local)

$8.1 BILLION
in labor income

107,918 new jobs created with an average compensation of $75,385
FUNDING OPPORTUNITIES
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 scientific & technology priorities
  - NCI priority areas
  - Strong potential for commercial success
  - Significant NCI oversight
  - 1 receipt date

- Areas of interest to commercial sector
# Grants vs. Contracts

<table>
<thead>
<tr>
<th>Grants</th>
<th>Contracts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator-defined within the mission of NIH</td>
<td>Defined by the NIH (focused)</td>
</tr>
<tr>
<td>NIH Center for Scientific Review (CSR)</td>
<td>NCI DEA (target 50% business reviewers)</td>
</tr>
<tr>
<td>May speak with any Program Officer</td>
<td>MUST contact the contracting officer</td>
</tr>
<tr>
<td>3 times/year for Omnibus</td>
<td>Only ONCE per year</td>
</tr>
<tr>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Based on score during peer review</td>
<td>If proposal scores well during peer review, must then negotiate to finalize deliverables with NIH</td>
</tr>
<tr>
<td>One final report (Phase I); Annual reports (Phase II)</td>
<td>Kick-off presentation, quarterly progress &amp; final reports</td>
</tr>
</tbody>
</table>

- **Scope of the proposal**
- **Peer Review Locus**
- **Questions**
- **Receipt Dates**
- **Set-aside of funds for particular areas?**
- **Basis for Award**
- **Reporting**
# Funding Opportunities

<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-19-272 (General)</td>
<td>PA-19-270 (General)</td>
<td>Standard Receipt Dates</td>
</tr>
<tr>
<td></td>
<td>PA-19-273 (Clinical Trial)</td>
<td>PA-19-271 (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></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>Development of Highly Innovative Tools and Technology for Analysis of Single Cells</td>
<td>PA-20-047</td>
<td>PA-20-025</td>
<td>August 3, 2020</td>
</tr>
<tr>
<td>Phase IIB Bridge Award</td>
<td>RFA-CA-20-033</td>
<td>Same as SBIR</td>
<td></td>
</tr>
<tr>
<td>Contract Solicitation</td>
<td>PHS 2021-1 (SBIR only)</td>
<td>No STTR</td>
<td>October 26, 2020</td>
</tr>
</tbody>
</table>
**SUPPLEMENT AWARDS**

Supplement Awards provide SBIR- and STTR-funded projects with additional support to assist awardees on their commercialization journey.

<table>
<thead>
<tr>
<th>TITLE</th>
<th>FOA</th>
<th>RECEIPT DATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Supplements to Existing NIH Grants</td>
<td>PA-18-591 (SBIR and STTR)</td>
<td></td>
</tr>
<tr>
<td>Accelerate the Development and Commercialization of Cancer-Related Innovations</td>
<td>NOT-CA-20-012 (SBIR only)</td>
<td>Rolling deadlines</td>
</tr>
<tr>
<td>Diversity Supplement</td>
<td>PA-19-034 (SBIR and STTR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PA-18-837 (SBIR and STTR)</td>
<td></td>
</tr>
<tr>
<td>SBIR/STTR Commercialization Readiness Pilot (CRP) Program, Technical Assistance Program</td>
<td>PAR-19-334 (SBIR and STTR)</td>
<td></td>
</tr>
</tbody>
</table>
SUPPLEMENTS TO EXISTING AWARDS

• PA-18-591 Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)
  • https://grants.nih.gov/grants/guide/admin_supp/index.htm

• Up to the amount of the current parent award
  • must reflect the actual needs of the proposed project

• Can be used for the following as long as they are within the original scope of the project
  • new experiments/aims as long as the research objectives
  • for unanticipated expenses from making modifications to the project that would improve the overall impact of the original project

• The project and budget periods must be within the currently approved project period for the existing parent award

• Contact your Program Officer to discuss before submitting

• Submit application using NIH Assist or grants.gov
SUPPLEMENTS TO PROMOTE DIVERSITY

• PA-18-837 Administrative Supplements to Promote Diversity in Research and Development Small Businesses-SBIR/STTR (Admin Supp Clinical Trial Not Allowed)

• For the purpose of this announcement, SBCs are encouraged to identify individuals from nationally underrepresented groups, as defined in the NIH Notice of Interest in Diversity (NOT-OD-18-129), women and/or socially and economically disadvantaged candidates. For the purpose of this FOA, the NIH is utilizing the SBA definition of socially and economically disadvantaged individuals. (https://www.sba.gov/contracting/government-contracting-programs/8a-business-development-program/eligibility-requirements/social-disadvantage-eligibility)

• Support for different career levels:
  • Undergraduate students; Baccalaureate and Masters Degree Holders; Graduate (predoctoral) and Health Professional Students; Post-doctoral investigators; Investigators Developing Independent Research Careers; PD(s)/PI(s) of research grants who are or become disabled and need additional support to accommodate their disability in order to continue to work on the research project.
PHASE IIB BRIDGE AWARD

- 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., ≥ 1:1 match)
In 2017, the 21 Bridge Award recipients leveraged $51M in NCI funding with ~$220M in third-party funds secured during the Bridge Award period for a ratio of: 

4 third-party dollars to 1 NCI dollar
## CONTRACTS FY2021 – IMPORTANT DATES

<table>
<thead>
<tr>
<th>Events</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-solicitation</td>
<td>July 9\textsuperscript{th}, 2020</td>
</tr>
<tr>
<td>Contract Solicitation (PHS-2021-1)</td>
<td>July 24\textsuperscript{th}, 2020</td>
</tr>
<tr>
<td>Receipt of Proposals (closing date)</td>
<td>October 26\textsuperscript{th}, 2020</td>
</tr>
</tbody>
</table>
## CONTRACTS FY2021 – ELIGIBILITY

The award is ALWAYS made to the small business concern.

<table>
<thead>
<tr>
<th>Applicant must be a Small Business Concern (SBC)</th>
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<td>Organized for-profit U.S. business (based in the U.S. and work performed in the U.S.)</td>
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<tr>
<td>&gt; 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these <em>(SBIR ONLY)</em></td>
</tr>
</tbody>
</table>

The eligibility for FY2021 Contracts is same as that for Omnibus Solicitations

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**SBIR DEVELOPMENT CENTER**

034.
CONTRACTS FY2021 – CONTACT INFORMATION

Contracting Office Address:
Office of Acquisitions
5601 Fishers Lane
3rd Floor, MSC 9821
Bethesda, Maryland 20892
United States

Primary Point of Contact:
George W Kennedy,
Contracting Officer
kennedyg@mail.nih.gov
Phone: 240-669-5170

Secondary Point of Contact:
Tiffany Chadwick,
Contracting Officer
tiffany.chadwick@nih.gov
Phone: 240-276-7293
<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Topic 413</td>
<td>Next Generation 3D Tissue Culture Systems with Tertiary Lymphoid Organs</td>
</tr>
<tr>
<td>Topic 414</td>
<td>Synthetic Biology Gene Circuits for Cancer Therapy</td>
</tr>
<tr>
<td>Topic 415</td>
<td>Applicator-Compatible Electronic Brachytherapy Sources for Cancer Radiotherapy</td>
</tr>
<tr>
<td>Topic 416</td>
<td>Self-Sampling Devices for HPV-Testing-Based Cervical Cancer Screening</td>
</tr>
<tr>
<td>Topic 417</td>
<td>Quantitative Imaging Software Tools for Cancer Diagnosis and Treatment Planning</td>
</tr>
<tr>
<td>Topic 418</td>
<td>3D Spatial Omics for Molecular and Cellular Tumor Atlas Construction</td>
</tr>
<tr>
<td>Topic 419</td>
<td>Understanding Cancer Tumor Genomic Results: Technology Applications for Providers</td>
</tr>
<tr>
<td>Topic 420</td>
<td>Single-Cell “Unbiased Discovery” Proteomic Technologies</td>
</tr>
<tr>
<td>Topic 421</td>
<td>Quantitative Biomimetic Phantoms for Cancer Imaging and Radiation Dosimetry</td>
</tr>
<tr>
<td>Topic 422</td>
<td>Spatial Sequencing Technologies with Single Cell Resolution for Cancer Research and Precision Medicine</td>
</tr>
<tr>
<td>Topic 423</td>
<td>Software to Address Social Determinants of Health in Oncology Practices</td>
</tr>
<tr>
<td>Topic 424</td>
<td>Digital Tools to Improve Health Outcomes in Pediatric Cancer Survivors</td>
</tr>
<tr>
<td>Topic 425</td>
<td>Information Technology Tools for Automated Analysis of Physical Activity, Performance, and Behavior from Images for Improved Cancer Health Tools</td>
</tr>
<tr>
<td>Topic 426</td>
<td>Tools and Technologies for Visualizing Multi-Scale Data</td>
</tr>
<tr>
<td>Topic 427</td>
<td>De-Identification Software Tools and Pipelines for Cancer Imaging Research</td>
</tr>
<tr>
<td>Topic 428</td>
<td>Cloud-Based Multi-Omic and Imaging Software for the Cancer Research Data Commons</td>
</tr>
<tr>
<td>Topic 429</td>
<td>Advanced Manufacturing to Speed Availability of Emerging Autologous Cell-Based Therapies</td>
</tr>
</tbody>
</table>

More information regarding NCI Contracts FY2021 will be updated [here](#).....
NCI SBIR INITIATIVES AND RESOURCES
NCI SBIR ASSISTANCE

Before Phase I  SBIR Phase I  SBIR Phase II  SBIR Phase IIB Bridge Award  Nonfederal Funds

Application Assistance Program

I-Corps at NIH
NCI Investor Initiatives
NCI Peer Learning and Networking (PLAN) Webinar
NCI Resources for Commercialization Workshops
CEO Roundtable
Connecting Awardees to Regulatory Experts (CARE)

Crossing the “Valley of Death”

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.

• Application period: closed. Please check back in Fiscal Year 2021.

• https://sbir.cancer.gov/aap

<table>
<thead>
<tr>
<th>AAP PROVIDES</th>
<th>AAP DOES NOT PROVIDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I SBIR/STTR application preparation support and review</td>
<td>Grant writer</td>
</tr>
<tr>
<td>Specific Aims page review and advice</td>
<td>Research plan development</td>
</tr>
<tr>
<td>Submission process coaching</td>
<td>Small business registration or NIH application submission services</td>
</tr>
</tbody>
</table>
AAP TIMELINE – 3 COHORTS IN 2020

Fiscal Year 2020

Cohort 1
Oct – Jan 6 2020
Applications Due

Cohort 2
Jan – Apr 6 2020
Applications Due

Cohort 3
Jun – Sep 7 2020
Applications Due

Oct 2019
Cohort 1
Applications Due

Jan 2020
Cohort 2
Applications Due

May 2020
Cohort 3
Applications Due
TRECS WORKSHOP

NCI SBIR Workshop on Translational Resources to Enhance Commercialization Success
Next Date: TBD

- 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

https://sbir.cancer.gov/programseducation/TRECS2020
PLAN WEBINAR SERIES

• Previous PLAN Webinar Topics:
  ➢ I-Corps at NIH
  ➢ Building an effective translational team
  ➢ NCI SBIR Phase IIB Bridge Award
  ➢ Protecting Intellectual Properties
  ➢ Insights into incubators and accelerator
  ➢ How to write a strong Phase II application

Peer Learning and Networking (PLAN) Webinar Series
Next date: June 23, 2020 (Topic: Introduction to 510(k))

• 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)*
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>
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</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></td>
<td><strong>I-Corps at NIH Learnings &amp; Pivot</strong></td>
<td>• Jun 2015 – Published technical paper in peer-reviewed journal, <em>Academic Radiology</em></td>
</tr>
<tr>
<td></td>
<td>• Thoracic surgeons “would do anything to localize tumors minimally invasively”</td>
<td>• Mar 2017 – Received Phase II STTR grant</td>
</tr>
</tbody>
</table>
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

• Applications open Summer 2020
  • Cohorts begin Fall 2020

• Networking
  • Ongoing Mentoring & Advice
  • Potential Partnerships

• In person or Virtual

• C-Level Executives of all awardees
  • 10-12 participants per cohort
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 2020
- 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
<table>
<thead>
<tr>
<th>CONTACT FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Center for Devices and Radiological Health (CDRH)</strong></td>
</tr>
<tr>
<td>DICE - Division of Industry and Consumer Education</td>
</tr>
<tr>
<td>Phone: 1(800) 638-2041 or (301) 796-7100</td>
</tr>
<tr>
<td>Email: <a href="mailto:DICE@fda.hhs.gov">DICE@fda.hhs.gov</a></td>
</tr>
<tr>
<td><strong>Center for Drug Evaluation and Research (CDER)</strong></td>
</tr>
<tr>
<td>SBIA - Small Business &amp; Industry Assistance</td>
</tr>
<tr>
<td>Phone: (866) 405-5367 or (301) 796-6707</td>
</tr>
<tr>
<td>Email: <a href="mailto:CDERSBIA@fda.hhs.gov">CDERSBIA@fda.hhs.gov</a></td>
</tr>
<tr>
<td><strong>Center for Biologics Evaluation and Research (CBER)</strong></td>
</tr>
<tr>
<td>MATTB - Manufacturers Assistance and Technical Training Branch</td>
</tr>
<tr>
<td>Phone: 240-402-8020 or 1-800-835-4709</td>
</tr>
<tr>
<td>Email: <a href="mailto:Industry.Biologics@fda.hhs.gov">Industry.Biologics@fda.hhs.gov</a></td>
</tr>
</tbody>
</table>
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

FAST-TRACK

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
TRANSITION GRANT

- More information on solicitation coming soon! Subscribe to NCI SBIR Newsletter to get updated information: sbir.cancer.gov/emails signup

- 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
# Talk to the Right Person

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Scientific Review Officer** | - Reviews applications for completeness  
- Assembles peer review team and ensures fair and unbiased evaluation of scientific and technical merit  
- Provides summary statement and/or technical evaluation minutes |
| **Program Officer** | - Your Go-To Person!  
- Write funding opportunity announcements  
- Provide scientific guidance to investigators pre- and post-award  
- Funding Decisions  
- Monitor the programmatic/scientific/technical aspects of a grant  
- Other Resources  
- Work in partnership with grants management staff and Office of Acquisition on post-award administration |
| **Grants Specialist** | - (Office of Grants Administration)  
- To discuss financial or grants administration issues  
- For interpretation of grants and contracts policies |
| **Contracts Specialist/Officer** | - (Office of Acquisition)  
- Discuss issues that will affect payment or deliverables  
- Manage compliance with contract terms and conditions.  
- Manage contract modifications |

REJECTION—YOU ARE NOT ALONE!

- Remember the three Rs:
  - **Review** your summary statement
  - **Revise** your application
  - **Resubmit** and try again!
- Talk to your program officer. We are here to help!

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**FUNDING SUCCESS RATE (FY11-15)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Original Application</th>
<th>Resubmission</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>3%</td>
<td>19%</td>
</tr>
<tr>
<td>2012</td>
<td>6%</td>
<td>28%</td>
</tr>
<tr>
<td>2013</td>
<td>7%</td>
<td>27%</td>
</tr>
<tr>
<td>2014</td>
<td>11%</td>
<td>29%</td>
</tr>
<tr>
<td>2015</td>
<td>11%</td>
<td>20%</td>
</tr>
</tbody>
</table>
Sample application: https://www.niaid.nih.gov/grants-contracts/sample-applications

**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...

055.
LET’S START TALKING!

Michael Weingarten, MA
Director
NCI SBIR Development Center

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

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

Ashim Subedee, PhD
Program Director
Cancer Therapeutics and
Diagnostics, Imaging, Cancer
Prevention and Control, Digital
Health, Investor Initiatives

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

Nancy Kamei, PharmD
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

Kory Hallett, PhD
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

Ashim Subedee, PhD
Program Director
Cancer Therapeutics and
Diagnostics, Imaging, Cancer
Prevention and Control, Digital
Health, Investor Initiatives

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!

056.
NCI SBIR SUPPORTING STAFF

Julienne Willis
Program Specialist
Program Support

Tamar Boghosian
Program Analyst
Budgets

Lisa Yeom
Communications Manager
External Communications, Traditional and Digital Media, Success Stories, and SBIR Events

Kehui Zhang
Program Analyst
Portfolio Analysis

Brittany Connors
Investor Relations Coordinator
Investor Initiatives, Executive Round Table

Bryce Gelling
Marketing Coordinator
Social Media, Events

Reema Railkar
Program Analyst & Fellow
I-Corps at NIH, SBIR Initiatives Support

Patti Swayne
Innovation Coordinator
Awardee Relations, Commercialization Programs

057.
• **NCI SBIR Monthly Office Hour**
  - 3rd Friday of each month (August date TBD)
  - Registration sheet to become available soon.
  - 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).

• **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/emailssignup

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Learn about our funding opportunities and resources from NCI SBIR program directors!
GET IN TOUCH WITH US!

- Keep in touch with your PD
  - Reach out to PDs at Conferences
  - Outreach Activities in your area
  - If you are in DC – stop by!
- Share success stories with us
  - Key Milestones
  - Fundraising Activities
- Web: https://sbir.cancer.gov
  Email: ncisbir@mail.nih.gov
  Twitter: @NCISBIR
THANK YOU


ncisbir@mail.nih.gov