NCI SBIR & STTR OVERVIEW: TRANSLATING CANCER TECHNOLOGIES FROM LAB TO MARKET

Jonathan Franca-Koh, PhD MBA
NCI SBIR Development Center
WHAT ARE SBIR & STTR?

• The NIH SBIR and STTR programs fund early stage small businesses that are seeking to commercialize innovative biomedical technologies.

• A leading source for early stage non-dilutive investment
  – Not a loan, no repayment
  – Intellectual property rights retained by the small business
  – Provides recognition, verification, and visibility
  – Helps provide leverage in attracting additional funding or support
PROGRAM SET ASIDES

❖ **Small Business Innovation Research (SBIR)**
Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization

*Federal agencies with an extramural R&D budget > $100M*

❖ **Small Business Technology Transfer (STTR)**
Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization

*Federal agencies with an extramural R&D budget > $1B*

<table>
<thead>
<tr>
<th>Set Aside</th>
<th>FY16</th>
<th>FY17</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.0%</td>
<td>3.2%</td>
</tr>
<tr>
<td>FY18</td>
<td>0.45%</td>
<td>0.45%</td>
</tr>
</tbody>
</table>

FY18 ~$1,073M (NIH)
FY18 ~$167M (NCI)
THREE-PHASE PROGRAM

FAST-TRACK (PH I & II)

PHASE I
- Proof-of-Concept
- Up to $300,000 over 6 to 12 months

PHASE II
- Research & Development
- Commercialization plan required
- Up to $2M over 2 years

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 3 years

NCI SBIR PHASE IIB BRIDGE AWARD
CROSSING THE VALLEY OF DEATH

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

✓ Applicant must be a Small Business Concern (SBC)
✓ Organized for-profit U.S. business
✓ 500 or fewer employees, including affiliates
✓ > 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 (SBIR ONLY)

> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

Award always made to small business
## 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 concern 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 concern (for profit), and minimum of 30% by a U.S. research institution (non-profit)</td>
</tr>
<tr>
<td><strong>ELIGIBILITY:</strong> The PD/PI’s primary employment (i.e., &gt;50%) MUST be with the SBC for the duration of the project period</td>
<td><strong>ELIGIBILITY:</strong> IP Agreement providing necessary IP rights to the SBC in order to carry out follow-on R&amp;D and commercialization</td>
</tr>
<tr>
<td></td>
<td>PI primary employment not stipulated (min. 10% effort to project)</td>
</tr>
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</table>
NIH has 27 Institutes and Centers
23 “separate” SBIR/STTR Programs

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 Deafness & Other Communication Disorders (NIDCD)
- 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 Eye Institute (NEI)
- National Institute of General Medical Sciences (NIGMS)
- 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 Nursing Research (NINR)
- National Institute on Minority Health & Health Disparities (NIMHD)
- National Center for Complementary & Integrative Health (NCCIH)
- 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)  Center for Information Technology (CIT)  Center for Scientific Review (CSR)

No funding authority
## 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-18-574 (General)</td>
<td>PA-18-575 (General)</td>
<td>September 5; January 5; April 5</td>
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<tr>
<td></td>
<td>PA-18-573 (Clinical Trial)</td>
<td>PA-18-576 (Clinical Trial)</td>
<td></td>
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<tr>
<td>SBIR Technology Transfer (technology transfer out of NIH intramural labs)</td>
<td>PA-18-705 (SBIR only)</td>
<td></td>
<td></td>
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<tr>
<td>Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings</td>
<td>PAR-18-801</td>
<td>PAR-18-802</td>
<td></td>
</tr>
<tr>
<td>SBIR IMAT (Innovative Molecular Analysis Technology) Development</td>
<td>PAR-18-303 (SBIR only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development of Highly Innovative Tools and Technology for Analysis of Single Cells</td>
<td>PA-17-147</td>
<td>PA-17-148</td>
<td></td>
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<tr>
<td>Tools for Cell Line Identification</td>
<td>PA-16-186 (SBIR only)</td>
<td></td>
<td></td>
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<tr>
<td>Phase IIB Bridge Award Open to federally-funded Phase II awardees</td>
<td>RFA-CA-18-011 (SBIR only)</td>
<td></td>
<td>Expired for 2018</td>
</tr>
<tr>
<td>Contract Solicitation</td>
<td>PHS 2019-1</td>
<td></td>
<td>October 22</td>
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<tr>
<td>Administrative Supplement</td>
<td>PA-18-591</td>
<td></td>
<td>Rolling</td>
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</table>
**APPLICATION & REVIEW 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

**1-2 Months**

IC staff prepare funding plan for IC Director

Advisory Council or Board recommend Approval

**3 Months**

IC allocates funds

Scientific Review Group evaluates scientific merit

Grantee conducts research
PRODUCT FOCUS

ACADEMIC GRANT

Expertise/Team
(Discovery Research)

Approach
(Appropriate for discovery)

Environment

Product
(optional)

Significance
(Knowledge increase)

Innovation
(What could be/theoretically possible)

SBIR/STTR GRANT

Expertise/Team

Phase I: Research and Development
Phase II: Commercial Development

Approach
(Product Development)

Environment

Science
(MANDATORY)

Innovation
(Competitive Advantage)

Significance
(Changing a paradigm)

Commercialization
FY13-17 SBIR and STTR SUCCESS RATES

<table>
<thead>
<tr>
<th>Phase</th>
<th>Applications Reviewed</th>
<th>Applications Awarded</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>4,672</td>
<td>778</td>
<td>16.7%</td>
</tr>
<tr>
<td>Phase II</td>
<td>454</td>
<td>158</td>
<td>34.8%</td>
</tr>
<tr>
<td>NCI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>1,087</td>
<td>139</td>
<td>12.8%</td>
</tr>
<tr>
<td>Phase II</td>
<td>68</td>
<td>23</td>
<td>33.8%</td>
</tr>
</tbody>
</table>
SBIR/STTR PORTFOLIO

FY2017 Portfolio (422 Projects)

- Therapeutics: 40%
- In Vitro Diagnostics: 20%
- Imaging: 10%
- Devices: 10%
- Cancer Biology: 5%
- Software & eHealth: 0%

- 86% Grants
- 13% Contracts
- 49% Phase I
- 51% Phase II
## GRANT vs. CONTRACT

<table>
<thead>
<tr>
<th></th>
<th>GRANT</th>
<th>CONTRACT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope of the proposal</strong></td>
<td>Investigator-defined within the mission of NIH</td>
<td>Defined by the NIH (focused)</td>
</tr>
<tr>
<td><strong>Peer Review Locus</strong></td>
<td>NIH Center for Scientific Review (CSR)</td>
<td>NCI DEA (target 50% business reviewers)</td>
</tr>
<tr>
<td><strong>Questions during solicitation period?</strong></td>
<td>May speak with any Program Officer</td>
<td>MUST contact the contracting officer</td>
</tr>
<tr>
<td><strong>Receipt Dates</strong></td>
<td>3 times/year for Omnibus</td>
<td>Only ONCE per year</td>
</tr>
<tr>
<td><strong>Set-aside of funds for particular areas?</strong></td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Basis for Award</strong></td>
<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><strong>Reporting</strong></td>
<td>One final report (Phase I); Annual reports (Phase II)</td>
<td>Kick-off presentation, quarterly progress &amp; final reports</td>
</tr>
<tr>
<td>Topic Title</td>
<td>Fast Track Accepted?</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>----------------------</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 382: Integrated Subcellular Microscopy and ‘Omics in Cancer Cell Biology</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 383: Smart, Multi-Core Biopsy Needle</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 384: Digital Healthcare Platform to Reduce Financial Hardship for Cancer Patients</td>
<td>Yes</td>
<td></td>
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<tr>
<td>NIH/NCI 385: Leveraging Connected Health Technologies to Address and Improve Health Outcomes of Long-Term Cancer Survivors</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 386: Novel Approaches for Local Delivery of Chemopreventive Agents</td>
<td>Yes</td>
<td></td>
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<tr>
<td>NIH/NCI 387: Multiplexed Preclinical Tools for Longitudinal Characterization of Immunological Status in Tumor and Its Microenvironment</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 388: In vitro Diagnostic for the Liver Flukes Opisthorchis viverrini and Clonorchis sinensis</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 389: Development of AI Tools to Understand and Duplicate Experts’ Radiation Therapy Planning for Prostate Cancer</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 390: Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 391: Drugs or Devices to Exploit the Immune Response Generated by Radiation Therapy</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 392: Clinical Trials of Systemic Targeted Radionuclide Therapies (FAST TRACK ONLY)</td>
<td>Fast Track Only</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 393: Sensing Tools to Measure Biological Response to Radiotherapy</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 394: Combinatory Treatment Modalities Utilizing Radiation to Locally Activate or Release Systemically Delivered Therapeutics</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 395: Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NIH/NCI 396: Imaging for Cancer Immunotherapies</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

https://sbir.cancer.gov/funding/contracts/currentcontracts
NIH & NCI ASSISTANCE: MORE THAN JUST $$$

NIH-Managed

NCI-Matched

Application Assistance Program

NCI Resources for Commercialization Workshops

NCI Peer Learning and Networking Webinar

I-Corps at NIH

NCI Investor Initiatives

Targeted NCI Workshops
(e.g. the 2016 NCI SBIR Workshop to facilitate the Development of Molecularly Targeted Radiotherapy)

NIH-Managed

Niche Assessment Program

Commercialization Assistance Program

Non-Federal Funds
NCI SBIR PROGRAM STAFF

Michael Weingarten, MA
Director
NCI SBIR Development Center

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

Patricia Weber, DrPH
Program Director
Digital Health, Therapeutics, Biologics, FRAC Workshop

Deepa Narayanan, MS
Program Director
Imaging, Clinical Trials, Radiation Therapy, Investigator Initiatives, FRAC Workshop

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

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

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

Let’s discuss your project!
Send Specific Aims to ncisbir@mail.nih.gov

Andrew J. Kurtz, PhD
Lead Program Director
Biologics, Small Molecules, Nanotherapeutics, Molecular Diagnostics, Bridge Award

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

Todd Haim, PhD
Program Director
Small Molecules, Biologics, Immunotherapy, Theranostics, Investigator Initiatives, FRAC Workshop

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

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

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

http://sbir.cancer.gov

http://sbir.nih.gov
THANKS FOR YOUR ATTENTION!

Jonathan Franca-Koh, PhD MBA
E-mail: francakohjc@mail.nih.gov

ncisbir@mail.nih.gov
@NCIsbir
bitly.com/NCIsbirFeedback