NCI SBIR & STTR
Funding, mentoring & networking assistance for next-generation cancer technologies

August 2, 2016
Deepa Narayanan
Program Director
National Cancer Institute SBIR Development Center

NIH = 27 Institutes & Centers
23 Participate in the SBIR/STTR Program

The Office of the Director (OD)
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 Child Health & Human Development (NICHD)
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 on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute on Deafness & Other Communication Disorders (NIDCD)
National Eye Institute (NEI)
National Human Genome Research Institute (NHGRI)
National Heart, Lung, & Blood Institute (NHLBI)
National Institute of Mental Health (NIMH)
National Institute of Neurological Disorders & Stroke (NINDS)
National Institute of General Medical Sciences (NIGMS)
National Institute of Nursing Research (NINR)

Congressionally-Mandated Programs

- 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
  FY2017 Level: 3.2%

- 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
  FY2017 Level: 0.45%

- ~$877M annually at NIH
  ~$136M annually at NCI
  FY2017 Level is Estimated 27% increase over FY2016
Reasons to Seek SBIR/STTR Funding

- Provides seed funding for innovative technology development
- Provides recognition, verification and visibility
- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)
- Not a loan: No repayment is needed, non-dilutive

Aruna Gambhir, MS, MBA
CEO and Co-Founder
Cellsight Technologies

"Innovators want to see that a technology works. SBIR funding has been critical to our company to show that our technology works."

SBIR Eligibility

- Applicant must be a Small Business Concern (SBC)
- Organized-for-profit U.S. business
- 500 or fewer employees, including affiliates
- PD/PI’s primary employment (i.e., > 50%) must be with SBC at the time of award and for duration of the project period
- > 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

STTR Eligibility

- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
  - Minimum 40% by small business concern
  - Minimum 30% by U.S. research institution
- U.S. Research Institution: College or University; Non-profit research organization; Federally-Funded R&D Center (FFRDC)
- Intellectual Property Agreement
  - Should provide the necessary IP rights (to the SBC) in order to carry out follow-on R&D and commercialization
- Principal Investigator’s primary employment may be with either the Small Business Concern or the research institution
SBIR and STTR Programs

**SBIR**
- Permits research institution partners (e.g., universities)
- Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities

**STTR**
- Requires research institution partners (e.g., universities)
- 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)

Award always made to small business

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**SBIR & STTR: Three-Phase Program**

**Phase I**
- Proof of Concept study
  - $150,000 over 6 months (SBIR) or 1 year (STTR)
  - Direct to Phase II (Skip Phase I)

**Phase II**
- Research & Development
- $1 million over 2 years

**Phase III**
- Commercialization
- Use of non-SBIR/STTR funds

**Fast Track Application**
- Combined Phase I & II

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**NCI Waiver Topics**

1. Therapeutics
   - e.g., Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies

2. In Vitro and In Vivo Diagnostics
   - e.g., Companion Diagnostics and Prognostic Technologies

3. Imaging Technologies
   - e.g., Agents, Devices, and Image-Guided Interventions

4. Devices for Cancer Therapy
   - e.g., Interventional Devices, Surgical, Radiation and Ablative Therapies

5. Agents for Cancer Prevention
   - but not “Technologies for Cancer Prevention”

6. Development of Low Cost Technologies for Global Health

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**APPENDIX A: PHS 2015-2 SBIR/STTR PROGRAM DESCRIPTIONS**

**Health**
1. Development of Companion Diagnostics
2. Vaccine Development for Cancer Prevention
3. Nanotechnology to Address “Undruggable” Drug Targets

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**THREE AWARD “CAPS”**

<table>
<thead>
<tr>
<th>PHASE</th>
<th>PHASE</th>
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<tbody>
<tr>
<td>Standard</td>
<td>$150K</td>
</tr>
<tr>
<td>Hard Cap</td>
<td>$225K</td>
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<tr>
<td>Waiver Cap</td>
<td>$300K</td>
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**APPENDIX B: NON-CONSULTATIVE SBIR/STTR APPLICATION GUIDANCE**

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NCI SBIR Development Center
Program Staff

Michael Neumann
Senior Program Manager
NCI SBIR Development Center

Greg Evans
Lead Program Director
Biologics, Small Molecules, Nanotherapeutics, Molecular Diagnostics

Michael Weingarten
Director
NCI SBIR Development Center

Jian Lou
Program Director
In Vitro Diagnostics, Theranostics, Preclinical Drug Development, Bioinformatics

Todd Haim
Program Director
Small Molecules, Biologics, Immunotherapeutics, Theranostics

Patricia Weber
Program Director
Digital Health, Therapeutics, Biologics, SBIR Investor Forum, FRAC Workshop

Deepa Narayanan
Program Director
Medical Devices, Clinical Trials, Radiation Therapy, SBIR Investor Forum, FRAC Workshop

Amir Rahbar
Program Director
In Vitro Diagnostics, Biologics, Therapeutics, Proteomics, SBIR Investor Forum

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

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Program Director
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PhD, MBA
Program Director
Cancer Biology, Biologics, Small Molecules, Cell Based Therapies

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

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sbir.cancer.gov @NCIsbir

NCI's SBIR/STTR Portfolio

- Therapeutics 39%
- Tools for Basic Research 8%
- In Vivo Diagnostics 21%
- Imaging Technologies 19%
- Electronic Cancer Therapy 7%
- Health IT & Software Tools 6%

NCI SBIR Development Center: 5 Core Activities

- Provide central oversight of all 400+ NCI-funded SBIR and STTR projects (Program Director role)
- Coach applicants in preparation of funding applications
- Conduct regular outreach events all over the U.S. (with state-based, BIO-like organizations)
- Maintain a network of investors, and broker personal connections between NCI SBIR companies and potential third-party investors/strategic partners
- Play active role in seeding emerging technology areas
Investigator-Initiated Grants

- Omnibus Solicitations (Phase I, Phase II, FastTrack)
  - PA-15-288 (SBIR) and PA-15-290 (STTR)
- Direct to Phase II Solicitation
  - PAR-15-289 (SBIR only)

We encourage applications for any topic within the NIH mission

Due: September 5, January 5, April 5

NCI SBIR Contract Funding Opportunities

http://sbir.cancer.gov/funding/contracts
Annual Solicitation for NCI SBIR Contract Topics

NCI scientific & technology priorities
Areas of interests to the commercial sector, based on market opportunity

Contract topics in NCI priority areas with strong potential for commercial success

NCI SBIR contracts (thousands)
% of total NCI SBIR

Fiscal Year
13%
8%
17%
25%
24%
33%
35%

SBIR Contracts vs. Grants

<table>
<thead>
<tr>
<th></th>
<th>SBIR Grants</th>
<th>SBIR Contracts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope of the proposal</td>
<td>Investigated relative within the mission of NIH</td>
<td>Defined narrowly by the NIDDK</td>
</tr>
<tr>
<td>Solicitation period</td>
<td>May speak with any Program Officer</td>
<td>MUST contact the contracting officer [<a href="mailto:eshanahan@mail.nih.gov">eshanahan@mail.nih.gov</a>]</td>
</tr>
<tr>
<td>Receipt Date</td>
<td>3 times/year for Omnibus</td>
<td>Only ONCE per year</td>
</tr>
<tr>
<td>Peer Review Location</td>
<td>NIH Center for Scientific Review (CSR)</td>
<td>NCI DEA (target 50% business reviewers)</td>
</tr>
<tr>
<td>Basis for Award</td>
<td>Peer review score/Program statement</td>
<td>Peer review score/negotiation of technical deliverables, budget</td>
</tr>
<tr>
<td>Reporting</td>
<td>One final report (Phase I); annual reports (Phase II)</td>
<td>Kickoff presentation, quarterly progress reports, final report, commercialization plan</td>
</tr>
<tr>
<td>Set-aside funds for particular areas?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Program Staff involvement</td>
<td>Low</td>
<td>High</td>
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Funding Opportunity Summary

- PHS-2017-1 “PHS Small Business Innovation Research (SBIR) Program Contract Solicitation”
- ONE application receipt date per year:
  - Published August 1, 2016

Receipt Date: October 21, 2016, 5:00 PM ET

- RFP can be found at:

- More info about NCI's topic areas:
  - [https://sbir.cancer.gov/funding/contracts/currentcontracts](https://sbir.cancer.gov/funding/contracts/currentcontracts)
NCI Contract Topics (Due October 21, 2016)

- NIH/NCI 355: Cell and Animal-Based Models to Advance Cancer Health Disparity Research
- NIH/NCI 356: Tools and Technologies for Monitoring RNA
- NIH/NCI 357: Innovative Tools for Quantifying Radio-Effector Dynamics in Cancer
- NIH/NCI 358: Highly Innovative Tools for Measuring Cancer Care Coordination
- NIH/NCI 359: Technologies for Differential Isolation of Exosomes and Oncosomes
- NIH/NCI 360: Innovative Tools for Interrogating Tumor Microenvironment Dynamics
- NIH/NCI 361: Informatics Tools to Measure Cancer Care Coordination
- NIH/NCI 362: Informative Tools to Monitor RNA Expression in Cancer
- NIH/NCI 363: Informative Tools to Evaluate the Effect of Cancer Therapeutics
- NIH/NCI 364: Informative Tools to Monitor Cancer Care Coordination
- NIH/NCI 366: Highly Innovative Tools for Quantifying Radio-Effector Dynamics in Cancer
- NIH/NCI 367: Informative Tools for Measuring Cancer Care Coordination
- NIH/NCI 368: Innovative Tools for Interrogating Tumor Microenvironment Dynamics
- NIH/NCI 369: Informative Tools for Measuring Cancer Care Coordination

http://sbir.cancer.gov/funding/contracts

NCI SBIR Phase IIB Bridge Award, Launched 2008

- Provides up to $1M per year for up to 3 years
- Open to any NIH-funded Phase II awardees 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)

NCI Total $42.8 M
Third-Party Investments $86.3 M
Leverage > 2 to 1

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Workshop on Federal Resources to Accelerate Commercialization

Bringing together NCI SBIR/STTR awardees to move funded technologies from bench to bedside

http://sbir.cancer.gov/programeducation/tracworkshop

- Speakers from FDA, CMS, USPTO, 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
- Brain storm sessions with other SBIR peers and NIH staff.

Program Description

- 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 need and market for the technology being developed.
  - Each team is expected to conduct over 100 interviews over 10 weeks.
- Format is focused on *Experiential Learning*
**Customer Development**

**Hypotheses Testing and Insight…**

- 3 cohorts offered NIH and NSF SBIR/STTR Phase I grants
- 38 teams conducted 4,264 customer discovery interviews
- 86% (on avg) found the program “very good” or “excellent”
- 86% (on avg) would recommend iCorps™ at NIH to other companies

“After going through iCorps we understood how to focus on a small subset of customers and understand our value propositions.”

**NIH Technical Assistance Programs**

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<thead>
<tr>
<th>Program</th>
<th>Brief Description</th>
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<tbody>
<tr>
<td>Niche Assessment Program</td>
<td>Explores uses of technology</td>
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<tr>
<td>Foresight S&amp;T</td>
<td>Determines competitive advantages</td>
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<tr>
<td>Commercialization Accelerator Program</td>
<td>Helps build strategic alliances</td>
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<tr>
<td>Larta, Inc.</td>
<td>Identifies other uses of technology</td>
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<tr>
<td></td>
<td>Determines competitive advantages</td>
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<td>“Menu” of technical assistance/training programs in:</td>
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<td></td>
<td>- Strategic/business planning</td>
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<td>- Risk management</td>
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<td>- Technology valuation</td>
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<td>- Manufacturing issues</td>
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<td>- Patent and licensing issues</td>
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<td>- Market entry strategy</td>
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<td>- Individualized mentoring/consulting</td>
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NIH Technical Assistance Programs (open to all eligible NIH SBIR/STTR awardees)
What Does It Take to Get Funded?
Tips on Applying

COMPETITIVE PROCESS

• NIH receives many strong SBIR/STTR proposals
• SBIR/STTR awards are highly competitive
  • Funding success rate around 15%
  • Resubmissions are very common
• You must prepare a strong application!

Know NIH Review Criteria

• Does the product address an important problem, and have commercial potential? Is there a market pull for the proposed product?
• Are design and methods well-developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?
• How novel is the technology/product and the approaches proposed to test its feasibility?
• Are the investigators, collaborators and consultants appropriately trained and capable of completing all project tasks?
• Does the scientific environment contribute to the probability of success? Facilities? Independence?
• Is the company’s business strategy one that has a high potential for success?
Before You Write an Application

- Consider your company’s strengths and how to exploit them
- Consider your company’s weaknesses and how to address them
- Contact an appropriate NIH Program Director in advance (at least 1 month before due date!), to discuss your specific aims and receive feedback
- Review similar, currently-funded NIH projects
  - NIH Project RePORTER

Search Previous Awards

http://projectreporter.nih.gov
What if you are not funded?

- Rejection is painful, BUT...
- Feedback provides a roadmap for next steps
  - Carefully review the Summary Statement (written critiques)
  - Use reviewer comments to improve your application
  - Discuss Summary Statement with your NIH Program Director
- Revise and resubmit the application
  - Introduction Page: Response to reviewer critiques
  - Be constructive not defensive
- Learn more about SBIR/STTR grants
  - Talk to successful applicants
  - Understand review process and dynamics - [http://scr.nih.gov](http://scr.nih.gov)

THANK YOU!

NCI SBIR Development Center
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