Bringing Medical Devices for Cancer to the Marketplace: 2014 Overview of the NCI Small Business Programs
Congressional Goals

1. Stimulate technological innovation
2. Use small business to meet Federal R&D needs
3. Increase private-sector commercialization innovations derived from Federal R&D
4. Foster participation by minority and disadvantaged persons in technological innovation

Small Business Innovation Development Act of 1982
Small Business Technology Transfer Act Act of 1992
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*

  - **Set Aside $$**
    
    FY14: 2.8%
    
    FY17: 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*

  - **Set Aside $$**
    
    FY14: 0.40%
    
    FY17: 0.45%

  ~$757 M in FY14 at NIH
  
  ~$119 M in FY14 at NCI
The annual SBIR/STTR budget for each participating Institute or Center (IC) is proportional to the total annual budget appropriation for that IC.
NCI SBIR/STTR Active Portfolio: Pipeline of 400+ Vetted Projects

- Therapeutics: 33%
- Devices for Cancer Therapy: 7%
- Imaging: 20%
- In Vitro Diagnostics: 21%
- Tools for Basic Research: 7%
- Health IT & Software Tools: 12%
• 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 required
  ☸ Doesn’t impact stock or shares in any way (i.e., non-dilutive)
• Intellectual property rights retained by the small business
**SBIR Eligibility Requirements**

- Applicant is a Small Business Concern (SBC)
- Organized for-profit U.S. business
- 500 or fewer employees, including affiliates
- PI’s primary employment (>50%) must be with the SBC at time of award & for duration of project
- > 50% U.S.- owned by individuals and independently operated*
  OR
- > 50% owned and controlled by other business concern/s that is/are > 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 *

*Formerly >= 51%; *New rule starting 1/28/13, NIH SBIR only
**STTR Eligibility**

- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
  - 40% by small business
  - 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
  - Allocation of IP rights (to SBC) and rights 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 (Critical Differences)

**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
NCI Has Multiple Small Business Solicitations
Know the Application Deadlines

- **SBIR & STTR Omnibus Solicitations for Grant Applications**
  
  *Release:* January
  *Receipt Dates:* April 5, August 5, and December 5

- **Solicitation of the NIH & CDC for SBIR Contract Proposals**
  
  *Release:* typically early August
  *Receipt Date:* *only once per year*, typically early November

- **See the NIH Guide for other Program Announcements (PA’s) and Requests for Application (RFA’s), i.e. grants**
  
  *Release:* Weekly
  *Receipt Dates:* Various

NCI Offers Three SBIR/STTR Award Stages

PHASE I – R41, R43 Grant, or Contract
- Feasibility Study
- $300K over < 12 months (rarely 18-24 months)

PHASE II – R42, R44 Grant, or Contract
- Full Research/R&D
- $2.0M over 2-3 years
- Commercialization plan required

PHASE III
- Commercialization Stage
- Use of non-SBIR/STTR Funds

Phase IIB Bridge Award

$1M per year for 3 years, with matching $$
(also NHLBI, NINDS)
• SBIR/STTR applicants must register at the SBA Company registry at SBIR.gov.

• VC-backed companies (VCOC, hedge fund, private equity firms) **CAN NOW** apply (**NIH SBIR only**).

• Applicants can request $5000 in Technical Assistance, beyond award cap. If requested, cannot participate in NIH Technical Assistance Programs.
• FY15 allows switching between STTR and SBIR mechanisms
  • Applicants may apply for Phase II SBIR funding based on Phase I STTR award or vice versa.

• Direct to Phase II applications for SBIR
<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>SBIR/STTR</th>
<th>Phase</th>
<th>Number of Applications Reviewed</th>
<th>Number of Applications Awarded</th>
<th>Success Rate</th>
<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>SBIR</td>
<td>Fast Track</td>
<td>313</td>
<td>49</td>
<td>15.7%</td>
<td>$13,981,386</td>
</tr>
<tr>
<td>2013</td>
<td>SBIR</td>
<td>Phase I</td>
<td>3,738</td>
<td>495</td>
<td>13.2%</td>
<td>$114,040,157</td>
</tr>
<tr>
<td>2013</td>
<td>SBIR</td>
<td>Phase II</td>
<td>542</td>
<td>178</td>
<td>32.8%</td>
<td>$136,348,846</td>
</tr>
<tr>
<td>2013</td>
<td>STTR</td>
<td>Fast Track</td>
<td>42</td>
<td>12</td>
<td>28.6%</td>
<td>$2,542,128</td>
</tr>
<tr>
<td>2013</td>
<td>STTR</td>
<td>Phase I</td>
<td>583</td>
<td>109</td>
<td>18.7%</td>
<td>$24,138,629</td>
</tr>
<tr>
<td>2013</td>
<td>STTR</td>
<td>Phase II</td>
<td>72</td>
<td>19</td>
<td>26.4%</td>
<td>$10,985,373</td>
</tr>
<tr>
<td><strong>2013</strong></td>
<td><strong>FY TOTAL</strong></td>
<td></td>
<td><strong>5,290</strong></td>
<td><strong>862</strong></td>
<td><strong>16.3%</strong></td>
<td><strong>$302,036,519</strong></td>
</tr>
</tbody>
</table>

Success rates are defined as the percentage of reviewed grant applications that receive funding.
Goal: To support the development, maturation, and dissemination of novel and potentially transformative next-generation technologies through an approach of balanced but targeted innovation in support of clinical, laboratory, or epidemiological research on cancer.

- Molecular and cellular analytical technologies for cancer detection and/or characterization *in vitro, in situ, or in vivo*

Next receipt dates: **May 28, 2014**
November and May through 2016

**Contact Dr. Amir Rahbar:** rahbaram@mail.nih.gov

http://sbir.cancer.gov/funding/technology
Goal: Accelerate development & commercialization of evidence-based consumer health IT to:

- Prevent or reduce the risk of cancer
- Facilitate patient-provider communication
- Improve disease outcomes in consumer & clinical settings

- Phase II or Fast-Track applications only
- Strong applicants will have a partnership with large business (e.g. commercial IT firm, EMR vendor, healthcare systems, etc.)

Next receipt dates: **April 5, 2014**
August 5, December 5 through 2014

Contact Dr. Patricia Weber: [weberpa@mail.nih.gov](mailto:weberpa@mail.nih.gov)
Know NIH SBIR/STTR Grant Review Criteria

Significance
- Does the product address an important problem, and have commercial potential? Is there a market pull for the proposed product?

Approach
- Are design and methods well-developed and appropriate? Are problem areas addressed?

Innovation
- How novel is the product and the approaches proposed to test its feasibility?

Investigator
- Is the investigator appropriately trained and capable of managing the project?

Environment
- Does the scientific environment contribute to the probability of success? Is the environment unique?

Commercialization
- Is the company’s business strategy one that has a high potential for success?
### NIH Timeline for New Grant Applications

#### 7-10 months

<table>
<thead>
<tr>
<th>Due Date</th>
<th>Scientific Review</th>
<th>Council Review</th>
<th>Award Date (earliest)</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 5</td>
<td>July</td>
<td>October</td>
<td>December</td>
</tr>
<tr>
<td>August 5</td>
<td>October</td>
<td>January</td>
<td>April</td>
</tr>
<tr>
<td>December 5</td>
<td>March</td>
<td>May</td>
<td>July</td>
</tr>
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</table>
Annual Solicitation for NCI SBIR Contract Topics

NCI scientific & technology priorities

Areas of interest 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

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI SBIR contracts (thousands)</td>
<td>$12,387</td>
<td>$7,757</td>
<td>$16,665</td>
<td>$25,020</td>
<td>$26,102</td>
<td>$37,406</td>
<td>$38,174</td>
</tr>
<tr>
<td>% of total NCI SBIR</td>
<td>13%</td>
<td>8%</td>
<td>17%</td>
<td>25%</td>
<td>24%</td>
<td>33%</td>
<td>35%</td>
</tr>
</tbody>
</table>
## NCI SBIR Contracts vs. Grants: What's the difference?

<table>
<thead>
<tr>
<th></th>
<th>SBIR Grants</th>
<th>SBIR Contracts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope of the proposal</strong></td>
<td>Investigator-defined within the mission of NIH</td>
<td><strong>Defined by the NIH (focused)</strong></td>
</tr>
<tr>
<td><strong>Questions during solicitation period?</strong></td>
<td>May speak with any Program Officer</td>
<td><strong>MUST</strong> 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>Peer Review Locus</strong></td>
<td>NIH Center for Scientific Review (CSR)</td>
<td><strong>NCI Division of Extramural Activities</strong></td>
</tr>
<tr>
<td><strong>Basis for Award</strong></td>
<td>Peer review score/ Program assessment</td>
<td>Peer review score/negotiation of technical deliverables, budget</td>
</tr>
<tr>
<td><strong>Reporting</strong></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><strong>Set-aside funds for particular areas?</strong></td>
<td>No</td>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td><strong>Program Staff Involvement</strong></td>
<td>Low</td>
<td><strong>High</strong></td>
</tr>
</tbody>
</table>
2013 NCI Contract Topics- last year

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

Therapy & Diagnosis
• 326 Development of Novel Therapeutic Agents that Target Cancer Stem Cells
• 327 Reformulation of Failed Chemotherapeutic Drugs
• 331 Development of a Biosensor-Based Core Needle Tumor Biopsy Device
• 332 Development of Radiation Modulators for Use During Radiotherapy

Advancing Cancer Research
• 328 Validation of 3D Human Tissue Culture Systems that Mimic the Tumor Microenvironment
• 329 Proteomic Analysis of Single Cells Isolated from Solid Tumors
• 330 Generation of Site-Specific Phospho-Threonine Protein Standards for Use in Cancer Assays

Health IT
• 333 Software Tools for the Development of Environmental Measures Related to Cancer Health Behavior and Resources
16 NCI Phase IIB Bridge Awards (to date)

NCI Total: $37,160,051
Third-Party Investments: $82,502,379
Leverage: > 2 to 1

Venture Capital: ~1/3
Strategic Partners: ~1/3
Individuals & Other: ~1/3

2009 NCI SBIR Investor Forum

NOVEMBER 5, 2009
8:00 AM – 6:00 PM

BOSTON UNIVERSITY TRUSTEE BALLROOM
1 Silber Way, 9th Floor
Boston, MA, USA 02115

BOSTON UNIVERSITY

2012 NCI SBIR Investor Forum

APRIL 18, 2012
Agilent Technologies, Aristote Room
5301 Stevens Creek Blvd
Santa Clara, CA 95051

National Cancer Institute

2010 NCI SBIR Investor Forum

NOVEMBER 9, 2010
9:00 AM – 6:00 PM PST

STANFORD UNIVERSITY
FRANCES C. ARRILLAGA ALUMNI CENTER
326 Galvez Street
Stanford, CA, USA 94305 – 6105

National Cancer Institute

2014 NCI SBIR Investor Forum

November 13, 2014
Agilent Technologies
5301 Stevens Creek Blvd.
Santa Clara, CA 95051

Genentech
A Member of the Roche Group
NCI SBIR Development Center

Staff

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

Christie Canaria, PhD
**AAAS Science & Technology Policy Fellow**
Policy, Outreach, Success Stories, Scientific Communications, SBIR Investor Forum, FRAC Workshop

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, FRAC Workshop

Todd Haim, PhD
**Program Director**
Small Molecules, Biologics, Immunotherapeutics, Theranostics, SBIR Investor Forum, FRAC Workshop

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

Jennifer Shieh, PhD
**Program Director**
Digital Health, Bioinformatics, Research Tools, Evaluation, SBIR Investor Forum, FRAC Workshop
More Information on NCI SBIR & STTR Website

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