Overview of the NIH SBIR/STTR Program

NCI SBIR Workshop on Federal Resources to Accelerate Commercialization

May 7, 2013

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SBIR/STTR Program Coordinator
Office of Extramural Research, NIH
SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM
2.7%
Set-aside program for small business concerns to engage in Federal R&D -- with potential for commercialization.

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM
0.35%
Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions -- with potential for commercialization.
Organized as for-profit U.S. business

Small: 500 or fewer employees, including affiliates

PD/PI’s primary employment must be with small business concern at time of award and for duration of project period

Greater than 50% U.S.- owned by individuals and independently operated or

Greater than 50% owned and controlled by other business concern/s that is/are greater than 50% owned and controlled by one or more individuals OR

Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these
STTR Eligibility Criteria

- Applicant is Small Business Concern
- Formal Cooperative R&D Effort
  - Minimum 40% by small business
  - Minimum 30% by U.S. research institution
- U.S. Research Institution
  - College or University; other non-profit research organization; Federal R&D center
- Intellectual Property Agreement
  - Allocation of Rights in IP and Rights to Carry out Follow-on R&D and Commercialization
NIH SBIR/STTR Budget Allocations FY2012

2.6% SBIR $632M
0.35% STTR $85M
Total FY2012 $717M
# NIH-wide SBIR/STTR Success Rates

<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>2011</td>
<td>SBIR</td>
<td>Fast Track</td>
<td>409</td>
<td>42</td>
<td>10.3%</td>
<td>$10,059,904</td>
</tr>
<tr>
<td>2011</td>
<td>SBIR</td>
<td>Phase 1</td>
<td>4,672</td>
<td>536</td>
<td>11.5%</td>
<td>$123,802,074</td>
</tr>
<tr>
<td>2011</td>
<td>SBIR</td>
<td>Phase 2</td>
<td>681</td>
<td>203</td>
<td>29.8%</td>
<td>$137,152,687</td>
</tr>
<tr>
<td>2011</td>
<td>STTR</td>
<td>Fast Track</td>
<td>42</td>
<td>4</td>
<td>9.5%</td>
<td>$813,900</td>
</tr>
<tr>
<td>2011</td>
<td>STTR</td>
<td>Phase 1</td>
<td>508</td>
<td>80</td>
<td>15.7%</td>
<td>$18,321,516</td>
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<tr>
<td>2011</td>
<td>STTR</td>
<td>Phase 2</td>
<td>103</td>
<td>37</td>
<td>35.9%</td>
<td>$20,977,584</td>
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<tr>
<td>2011 FY TOTAL</td>
<td></td>
<td></td>
<td>6,415</td>
<td>902</td>
<td>14.1%</td>
<td>$311,127,665</td>
</tr>
<tr>
<td>2012</td>
<td>SBIR</td>
<td>Fast Track</td>
<td>358</td>
<td>57</td>
<td>15.9%</td>
<td>$13,985,802</td>
</tr>
<tr>
<td>2012</td>
<td>SBIR</td>
<td>Phase 1</td>
<td>4,287</td>
<td>667</td>
<td>15.6%</td>
<td>$154,237,890</td>
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<tr>
<td>2012</td>
<td>SBIR</td>
<td>Phase 2</td>
<td>557</td>
<td>222</td>
<td>39.9%</td>
<td>$153,650,162</td>
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<tr>
<td>2012</td>
<td>STTR</td>
<td>Fast Track</td>
<td>32</td>
<td>11</td>
<td>34.4%</td>
<td>$2,840,632</td>
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<tr>
<td>2012</td>
<td>STTR</td>
<td>Phase 1</td>
<td>542</td>
<td>110</td>
<td>20.3%</td>
<td>$23,857,700</td>
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<tr>
<td>2012</td>
<td>STTR</td>
<td>Phase 2</td>
<td>71</td>
<td>28</td>
<td>39.4%</td>
<td>$18,240,418</td>
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<tr>
<td>2012 FY TOTAL</td>
<td></td>
<td></td>
<td>5,847</td>
<td>1,095</td>
<td>18.7%</td>
<td>$366,812,604</td>
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http://sbir.nih.gov

Standard Due Dates: Apr 5; Aug 5; Dec 5
• NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation **
  “Parent” FOAs: SBIR: PA-13-088  STTR: PA-13-089
  Release: January
  Standard Due Dates: April 5, Aug 5, Dec 5
  (AIDS/AIDS-related: May 7, Sept 7, Jan 7)

• SBIR Contract Solicitation (NIH, CDC)
  Release: August  November 13th, 2012 close date

• NIH Guide for Grants and Contracts
  Release: Weekly Receipt dates specified in each FOA
  (http://grants.nih.gov/grants/guide/index.html)
Important changes in this year’s Omnibus Grant Solicitations


- New SBIR/STTR award budget HARD caps in place

 Award Guidelines

<table>
<thead>
<tr>
<th>Program</th>
<th>Phase I</th>
<th>Phase II</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBIR</td>
<td>$150,000</td>
<td>$1,000,000</td>
</tr>
<tr>
<td>STTR</td>
<td>$150,000</td>
<td>$1,000,000</td>
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</table>

Award Hard Caps – cannot exceed

<table>
<thead>
<tr>
<th>Program</th>
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<th>Phase II</th>
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</thead>
<tbody>
<tr>
<td>SBIR</td>
<td>$225,000</td>
<td>$1,500,000</td>
</tr>
<tr>
<td>STTR</td>
<td>$225,000</td>
<td>$1,500,000</td>
</tr>
</tbody>
</table>
Important changes in this year’s Omnibus Grant Solicitations

- Technical Assistance option
  - NIH offers distinct **technical assistance programs** to SBIR Phase I and Phase II awardees (Niche & CAP)
  - Applicants wishing to utilize their own technical assistance vendor are required to include this in your budget and provide a detailed budget justification.
  - Please note, if funds are requested to utilize your own technical assistance vendor and an award is made, the awardee is not eligible to apply for the NIH-provided technical assistance program for the phase of their award.
New provisions **NOT** implemented in this year’s Omnibus Grant Solicitations at this time

1. **No Switching mechanisms at Phase II**
   - Applicants **cannot** apply for Phase II SBIR funding based on a Phase I STTR award or conversely a Phase II STTR based on a Phase I SBIR award. Similarly, applicants **cannot** apply for a Phase IIB SBIR or STTR based on a Phase II STTR or SBIR award, respectively.

2. **No Direct Phase II applications (pilot FOAs when implemented)**

**Why not?** NIH is currently updating its electronic systems and forms for these provisions.
3. VC-backed companies (VCOC, Hedge fund, private equity firm) **CANNOT** apply at this time.

4. SBA Company registry at SBIR.gov.

**Why not?** SBA’s new eligibility rules went into effect after NIH issued the Omnibus solicitations. NIH is currently updating its electronic systems and forms for these provisions.
• NIH intends to revise, amend or re-issue the Omnibus solicitations in the middle of 2013 to implement additional reauthorization provisions as guidance from the SBA is received and electronic system and form updates at NIH and SBA are implemented.
• SBIR/STTR grant applications must be submitted electronically. SBIR contract proposals still in paper form.

• **Registrations are required!!!**
  – System for Award Management (SAM)
  – Grants.gov (company)
  – eRA Commons (company and all PD/PIs)
    • Coming Soon --- SBA company registry at SBIR.gov

Stay Informed…

- **NIH Guide for Grants and Contracts** (weekly notification)
  
  http://grants.nih.gov/grants/guide/listserv.htm

- **NIH SBIR/STTR Notification**

  Send email to LISTSERV@LIST.NIH.GOV with the following text in the message body:

  subscribe SBIR-STTR your name.
Save the Date!

15th Annual NIH SBIR/STTR Conference

• October 28-30, 2013
• Sioux Falls, South Dakota
• Hosted by University of South Dakota Research Park, Inc.

• Stay tuned to NIH SBIR website and listserv for details!
sbir@od.nih.gov

Follow us @NIHsbir

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