Exploring the NIH SBIR/STTR Funding Programs

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Nebraska Business Development Center

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SBIR/STTR Program Manager
Office of Extramural Research, NIH
• SBIR/STTR Program Overview
• NIH SBIR/STTR Program Specifics
• Reauthorization Updates
• Solicitations and Funding Opportunities
• The NIH Peer-Review Process
• Transitioning to the Marketplace
• Question & Answer
Most Important Piece of Advice

• Talk to an HHS Program Officer about your application and **SUBMIT EARLY** (days not hours and minutes)!
  
  o Program Officer contact information found on the HHS Agency Contact webpage
  
  o Questions about who to contact? Email sbir@od.nih.gov
What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are one of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

In Fiscal Year 2015, NIH’s SBIR and STTR programs will invest over 780 million dollars into early-stage, health and life science companies that are creating a wide range of innovative technologies that align with NIH’s mission to improve health and save lives. A key objective of this work is translating promising technologies to the private sector through strategic public and private partnerships, so that life-saving innovations reach consumer markets.

We invite you to explore our website to learn more about NIH’s SBIR & STTR programs, or get started on an application!
SBIR/STTR Application Process Infographic

Use this interactive chart that contains helpful information to guide you through the NIH SBIR/STTR application process. Click though the chart for answers to your related questions.

- Start the SBIR/STTR Application Process Infographic
- Confirm Your Small Business Concern Meets Eligibility Requirements
- Develop an Innovative Research Idea
- Five Required Registrations: (Overview)
- SBIR Omnibus
- Targeted

New to SBIR/STTR
Where to Start
**SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

**SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization
SBIR Purpose and Goals

- Stimulate technological innovation
- Use small business to meet federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from federal R&D

Small Business Innovation Development Act of 1982
P.L. 112-81 Re-Authorizes program through FY2017
• Stimulate and foster scientific and technological innovation through cooperative research and development carried out *between* small business concerns and research institutions

• Foster *technology transfer* between small business concerns and research institutions

*Small Business Research and Development Enhancement Act of 1992*

P.L. 112-81 Re-Authorizes program through FY2017
### SBIR/STTR Budgets by Agency FY2015

#### Agencies with SBIR and STTR Programs

<table>
<thead>
<tr>
<th>Agency</th>
<th>Budget</th>
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</thead>
<tbody>
<tr>
<td>Department of Defense (DOD)</td>
<td>$1,070 B</td>
</tr>
<tr>
<td>Department of Health and Human Services (HHS), including NIH*</td>
<td>$797.0 M</td>
</tr>
<tr>
<td>Department of Energy (DOE), including ARPA-E</td>
<td>$206.1M</td>
</tr>
<tr>
<td>National Aeronautics and Space Administration (NASA)</td>
<td>$180.1 M</td>
</tr>
<tr>
<td>National Science Foundation (NSF)</td>
<td>$176.0 M</td>
</tr>
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</table>

#### Agencies with SBIR Programs

<table>
<thead>
<tr>
<th>Agency</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Department of Agriculture (USDA)</td>
<td>$25.3M</td>
</tr>
<tr>
<td>Department of Homeland Security (DHS): S&amp;T and Domestic Nuclear Detection Office (DNDO)</td>
<td>$17.7 M</td>
</tr>
<tr>
<td>Department of Commerce: NOAA and NIST*</td>
<td>$8.4M</td>
</tr>
<tr>
<td>Department of Transportation (DOT)</td>
<td>$7.9 M</td>
</tr>
<tr>
<td>Department of Education (ED)</td>
<td>$7.5 M</td>
</tr>
<tr>
<td>Environmental Protection Agency (EPA)</td>
<td>$4.2 M</td>
</tr>
</tbody>
</table>

~ $2.5B in FY15 across all agencies
<table>
<thead>
<tr>
<th></th>
<th>2016 Budget</th>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>$763M</td>
<td></td>
<td>$114M</td>
</tr>
<tr>
<td>CDC</td>
<td>$9M</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>ACL (NIDILRR)</td>
<td>$2.7M</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>FDA</td>
<td>$1.55M</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>ACF</td>
<td>$93.5K</td>
<td>N/A</td>
<td></td>
</tr>
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</table>
NIH SBIR/STTR 3-Phase Program

**Phase I Feasibility Study**
- **Budget Guide:** $150K for SBIR and STTR
- **Project Period:** 6 months (SBIR); 1 year (STTR)

**Phase II Full Research/R&D**
- $1M for SBIR and STTR, over two years

**Phase IIB Competing Renewal/R&D**
- Clinical R&D; Complex Instrumentation/Tools to FDA
  - Many, but not all, IC’s participate
  - Varies-$1M per year; up to 3 years

**Phase III Commercialization Stage**
- NIH, generally, not the “customer”
  - Consider partnering and exit strategy early
SBIR Eligibility Criteria

• Organized as for-profit US business

• Small: 500 or fewer employees, including affiliates

• Work must be done in the US (with few exceptions)

• Individual Ownership:
  o Greater than 50% US-owned by individuals and independently operated OR
  o 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
  o 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 (For FOAs after 1/28/2013 NIH; 7/10/14 CDC)
STTR Eligibility Criteria

• Applicant is a Small Business Concern

• Formal Cooperative R&D Effort
  o Minimum 40% by small business
  o Minimum 30% by US research institution

• US Research Institution
  o College or university; other non-profit research organization; Federal R&D center

• Intellectual Property Agreement
  o Allocation of rights in IP and rights to carry out follow-on R&D and commercialization
### SBIR and STTR Critical Differences

<table>
<thead>
<tr>
<th>Partnering Requirement</th>
<th>SBIR</th>
<th>STTR</th>
</tr>
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<tbody>
<tr>
<td>Permits partnering</td>
<td></td>
<td>Requires a non-profit research institution partner (e.g. university)</td>
</tr>
</tbody>
</table>

| Work Requirement | Guidelines: May outsource 33% (Phase I) 50% (Phase II) | Minimum Work Requirements: 40% small business 30% research institution partner |

| Principal Investigator | Primary employment (>50%) must be with the small business | PI may be employed by either the research institution partner or small business |

**Award is always made to the small business**
Important Facts to Remember

- Eligibility is determined at time of award
- PD/PI is not required to have a Ph.D./M.D.
- PD/PI is required to have expertise to oversee project scientifically and technically
- Applications may be submitted to different agencies for similar work
- Awards may not be accepted from different agencies for duplicative projects
• SBIR/STTR Program Overview
• **NIH SBIR/STTR Program Specifics**
• Reauthorization Updates
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• Question & Answer
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
NIH SBIR/STTR Budget Allocations FY2016

3.0% SBIR $763M
0.45% STTR $114M
Total FY16 $877M
NIH SBIR/STTR
Fast-Track

Discovery
Phase I
Feasibility

Development
Phase II
Full R/D

Competing Renewal Award
Phase IIB
$3M for up to 3 years

Additional R/D

Commercialization
Phase III

- Simultaneous submission and review of Phase I and II
- Phase I is awarded
- Milestones/aims of Phase I are assessed by program staff BEFORE Phase II is awarded

Phase I ➔ Phase II
Fast-Track
Direct to Phase II
NIH SBIR/STTR Direct to Phase II

**Feasibility**
- Phase I
- SBIR only
- Bypass Phase I grant
- Must have completed Phase-I-type R&D (i.e. feasibility) to move directly into a Phase-II
- SEPARATE FOAs: [https://sbir.nih.gov/funding#phase2](https://sbir.nih.gov/funding#phase2)
- Not all ICs Participate

**Development**
- Phase II
- Fast-Track
- Direct to Phase II

**Competing Renewal Award**
- Phase IIIB
- $3M for up to 3 years

**Commercialization**
- Phase III

**Phases**
- Discovery
- Development
- Commercialization
• SBIR/STTR Phase II awardee

• Technologies that require extraordinary time/effort to develop, and often require FDA regulatory approval

• Awards up to $1M/year for up to 3 years

• IC must accept Competing Renewal applications (NIA, NIAAA, NIAID, NICHD, NIDA, NIDCD, NIDDK, NEI, NIGMS NHLBI, NIMH, NINDS, NCATS, ORIP, NCI, NHLBI, NINDS)

**Contact NIH Program Staff to discuss!**
Commercialization Readiness Pilot (CRP)

- **Discovery Phase I**
- **Development Phase II**
- **Competing Renewal Award Phase IIB**
- **Commercialization Phase III**

$3M for up to 3 years

Webinar materials available at sbir.nih.gov

**PAR16-026**: Technical Assistance
**PAR16-027**: Technical Assistance and Late Stage Development

Contact NIH Program Staff to discuss!
• CRP may fund work that is not typically supported through SBIR/STTR Phase II or Phase IIB awards, including:
  o Preparation of documents for a Food and Drug Administration (FDA) submission
  o Development of an intellectual property strategy
  o Investigational New Drug (IND)-enabling studies
  o Clinical studies
  o Manufacturing costs
  o Regulatory assistance
  o Subcontracted work to other institutions, including contract research organizations (CRO)
  o A combination of services

• HHS CRP Informational Webinar (December 2, 2015)
  o Webinar, slides, transcript @ http://grants.nih.gov/CRP%20Webinar
Grant Success Rate of SBIR/STTR 2015 by Phase

*STTR does not offer Direct Phase II

**In FY15, there were no Phase IIB STTRs
<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>SBIR/STTR</th>
<th>Phase</th>
<th>No. Applications Reviewed</th>
<th>Number Applications Awarded</th>
<th>Success Rate</th>
<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015 SBIR</td>
<td>Fast Track</td>
<td>337</td>
<td>66</td>
<td>19.6%</td>
<td>$18,157,545</td>
<td></td>
</tr>
<tr>
<td>2015 SBIR</td>
<td>Phase I</td>
<td>3,425</td>
<td>514</td>
<td>15.0%</td>
<td>$117,110,555</td>
<td></td>
</tr>
<tr>
<td>2015 SBIR</td>
<td>Total Phase II</td>
<td>823</td>
<td>241</td>
<td>29.3%</td>
<td>$179,946,727</td>
<td></td>
</tr>
<tr>
<td>2015 SBIR</td>
<td>Regular Phase II</td>
<td>442</td>
<td>163</td>
<td>36.9%</td>
<td>$113,088,150</td>
<td></td>
</tr>
<tr>
<td>2015 SBIR</td>
<td>Direct Phase II</td>
<td>347</td>
<td>65</td>
<td>18.7%</td>
<td>$55,150,363</td>
<td></td>
</tr>
<tr>
<td>2015 SBIR</td>
<td>Phase IIB</td>
<td>34</td>
<td>13</td>
<td>38.2%</td>
<td>$11,708,214</td>
<td></td>
</tr>
<tr>
<td>2015 STTR</td>
<td>Fast Track</td>
<td>61</td>
<td>10</td>
<td>16.4%</td>
<td>$2,171,909</td>
<td></td>
</tr>
<tr>
<td>2015 STTR</td>
<td>Phase I</td>
<td>911</td>
<td>149</td>
<td>16.4%</td>
<td>$33,782,224</td>
<td></td>
</tr>
<tr>
<td>2015 STTR</td>
<td>Total Phase II</td>
<td>87</td>
<td>31</td>
<td>35.6%</td>
<td>$21,597,183</td>
<td></td>
</tr>
<tr>
<td>2015 STTR</td>
<td>Regular Phase II</td>
<td>87</td>
<td>31</td>
<td>35.6%</td>
<td>$21,597,183</td>
<td></td>
</tr>
<tr>
<td>2015 FY TOTAL</td>
<td></td>
<td>5,644</td>
<td>1,011</td>
<td>17.9%</td>
<td>$372,766,143</td>
<td></td>
</tr>
</tbody>
</table>

• SBIR/STTR Program Overview
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See [NOT-OD-13-071](https://not-od.nih.gov) for details.

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>
</tr>
</tbody>
</table>

### Award Hard Caps - cannot exceed

<table>
<thead>
<tr>
<th>Program</th>
<th>Phase I</th>
<th>Phase II</th>
</tr>
</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>
Agencies (not applicants) must apply for a waiver from the SBA for budgets over the hard cap ($225,000 for Phase I and $1,500,000 for Phase II).

SBA has approved a topics list, which allows budgets to exceed the hard caps as long as the project topics are on the list.

Pre-approved topics list is Appendix A in regular topics document.

The approval is good for the 2016 SBIR/STTR Omnibus, and any FOA that falls on the topic list, including the Direct Phase II FOAs.
• Small business concerns that are majority-owned by multiple venture capital operating companies (VCOCs), hedge funds and/or private equity firms ARE NOW ELIGIBLE to apply to NIH and CDC SBIR

• See NOT-OD-13-071

• SBIR and STTR VCOC forms available online

*Note: SBIR VCOC form also used for SBIR contracts
Switching between SBIR and STTR

NIH SBIR/STTR applicants may now ‘switch’ programs at Phase II or Phase IIB to any active NIH SBIR/STTR solicitation.

**Which means:**

- Phase I STTR Awardees may apply for NIH SBIR or STTR Phase II
- Phase I SBIR Awardees may apply for NIH SBIR or STTR Phase II
- Phase II STTR Awardees may apply for NIH SBIR or STTR Phase IIB
- Phase II SBIR Awardees may apply for NIH SBIR or STTR Phase IIB

*Note that not all NIH Institutes and Centers accept Phase IIB applications.*
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Each year NIH issues an SBIR and an STTR Omnibus grant solicitation for small businesses, which allow small businesses to submit researcher-initiated projects that are within NIH's mission. The 2015 Program Descriptions and Research Topics document explains priority research areas for the US Department of Health and Human Service (HHS) SBIR and STTR programs at each of the 24 participating NIH Institutes and Centers (ICs), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA) and the Administration for Children and Families (ACF). You may perform a “Ctrl-F” keyword search to identify NIH ICs that have overlapping program priorities with your research topic, and also use NIH Matchmaker to conduct keyword searches of your topic to identify ICs that have funded research in your area. With any specific idea, you should speak directly with the program official to gauge their interest. Click here to view the Fiscal Year 2015 SBA approved topics for budget waivers.

NIH's Institutes and Centers also issue targeted funding opportunity announcements for certain research areas, as well as an annual NIH SBIR contract. Find out more about the different NIH funding opportunity announcements.

Funding Opportunities for U.S. Small Businesses

If your small business concern (SBC) decides to apply, please use the SF424 (R&R) SBIR/STTR Application Guide (Version C), and the Annotated SF424 (R&R) SBIR/STTR Form Set (FORMS-C) for step-by-step instructions on how to complete the application.

Both grant and contract applications require separate forms or appendices to be attached. Whether an attachment is required or not is often based on how you answer specific questions throughout the application (ie: related to human subject's research). You may find these forms or appendices in your grant application package that you download from Grants.gov, or you may also access them online, here.

https://sbir.nih.gov/funding
Solicitations and Due Dates

- NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation “Parent” FOAs: SBIR: PA-16-302  STTR: PA-16-303
  Release: June 3, 2016
  Standard Due Dates: September 5, January 5, April 5

- SBIR Contract Solicitation (NIH, CDC) - Program Solicitation PHS 2017-1 (SBIRs Only)
  NIH Guide Notice NOT-OD-16-123
  Release: August 1, 2016  Close: October 21, 2016 (5pm EDT)

- NIH Guide for Grants and Contracts
  Release: Weekly receipt dates specified in each FOA
Our Ideas: Suggested topic areas*

- Biodefense
- Biosensors
- Nanotechnologies
- Bioinformatics
- Diagnostic and Therapeutic Devices
- Telehealth
- Proteomics / Genomics

- Biosilicon devices
- Biocompatible materials
- Acousto-optics / opto-electronics
- Health IT
- Imaging devices
- Genetically engineered proteins
- ...
YOUR Ideas: Investigator-initiated R&D

- Research projects related to the NIH mission
- “Other” areas of research within the mission of an awarding component

Keyword Search the Solicitation
Ctrl + F
NIH Guide for Grants and Contracts

- High priority areas for ICs
- Various IC participation
- Nuances:
  - Various due dates
  - Additional review criteria
  - Limited funds
  - Varying project periods
  - Etc

http://sbir.nih.gov/funding#targeted
<table>
<thead>
<tr>
<th></th>
<th>Omnibus</th>
<th>Targeted</th>
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</thead>
<tbody>
<tr>
<td>Due Dates</td>
<td>Standard Due Dates</td>
<td>Standard or Customized Due Dates</td>
</tr>
<tr>
<td>Review</td>
<td>SBIR/STTR panels at CSR</td>
<td>SBIR/STTR panels at CSR OR SBIR/STTR panel at IC</td>
</tr>
<tr>
<td>Application</td>
<td>Follow SF424 R&amp;R SBIR/STTR Application Guide</td>
<td>Follow SF424 R&amp;R SBIR/STTR Application Guide AND any</td>
</tr>
<tr>
<td>Instructions</td>
<td>&amp; Annotated Form Set</td>
<td>additional instructions in FOA</td>
</tr>
</tbody>
</table>

**Read FOA very carefully!**
See **NOT-OD-15-038**

**Old SBIR/STTR Standard Due Dates**

<table>
<thead>
<tr>
<th>Cycle I Due Date</th>
<th>Cycle II Due Date</th>
<th>Cycle III Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 5</td>
<td>August 5</td>
<td>December 5</td>
</tr>
</tbody>
</table>

**Current SBIR/STTR Standard Due Dates**

*Effective September 5, 2015, *(no) AIDS standard due dates)*

<table>
<thead>
<tr>
<th>Cycle I Due Date</th>
<th>Cycle II Due Date</th>
<th>Cycle III Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 5</td>
<td>January 5</td>
<td>April 5</td>
</tr>
</tbody>
</table>
SBIR/STTR grant applications and SBIR contract proposals must be submitted **electronically**.

**Registrations are required!!!**

- DUNS Number (Company)
- System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov

- Helpful [NIH Grants Registration Infographic](#)

- For contracts, submit proposals with [electronic Contract Proposal Submission](#) (eCPS) website
ASSIST - A New Submission Option

ASSIST is optional, not required!
Excerpt from single-project FOA in NIH Guide...

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. Learn more.

Apply Online Using ASSIST
Apply Using Downloadable Forms
Revised NIH Late Submission Policy

- **NOT-OD-15-039** issued on 12/17/2014

- **Two week window** of consideration after the application due date for ALL grant applications, all mechanisms (PA, PAR, RFA)

- SBIR/STTR previously had 1 week window

- Supersedes old policy **NOT-OD-11-035**
What is a Women-Owned Small Business (WOSB)?

- A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women (who must be US citizens)
- The firm must be “small” in its primary industry in accordance with SBA’s size standards for that industry
- SBCs self certify on the SF 424 (R&R) Form
What is a **Socially and Economically Disadvantaged Business (SDB)**?

- The firm must be 51% or more owned and control by one or more disadvantaged persons

- The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged

- The firm must be small, according to SBA’s size standards

- You must self-certify by registering your business in the [System for Award Management](https://www.sam.gov)
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Applicant initiates research idea

Small Business Concern confirms Eligibility

Program Staff

 NIH Center for Scientific Review assigns to IC and IRG Referral Office

IC staff prepare funding plan for IC Director

Program Staff

Grants Management

Scientific Review Group evaluates scientific merit

Scientific Review Officer

Advisory Council or Board recommend Approval

Program Staff

NIH allocates funds

Grantee conducts research
<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>Sept 5</td>
<td>Oct/Nov</td>
<td>Jan/Feb</td>
<td>March</td>
</tr>
<tr>
<td>Jan 5</td>
<td>Feb/Mar</td>
<td>May/June</td>
<td>July</td>
</tr>
<tr>
<td>April 5</td>
<td>June/July</td>
<td>Aug</td>
<td>Sept or Dec</td>
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</tbody>
</table>
Common Application Problems

- No Significance
  - Unimportant problem, unconvincing case for commercial potential or societal impact
- Inadequately defined test of feasibility
- Lack of innovation
- Diffuse, superficial, or unfocused research plan
- Questionable reasoning in experimental approach
  - Failure to consider potential pitfalls and alternatives
- Lack of experience with essential methodologies
- Unfamiliar with relevant published work
- Unrealistically large amount of work proposed
**Most Important Piece of Advice**

- Talk to an HHS Program Officer about your application and **SUBMIT EARLY** (days not hours and minutes)!
  
  - Program Officer contact information found on the [HHS Agency Contact webpage](#)
  
  - Questions about who to contact? Email sbir@od.nih.gov
Agenda

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NIH Technical Assistance Programs

Helping companies cross the “Valley of Death”

Phase I

Phase II

Phase III

Niche Assessment Program (NAP)

Commercialization Accelerator Program (CAP)

Early-Stage Technology

Market-Ready Technology

Valley of Death

Phase IIB

?”
Niche Assessment Program Foresight S&T (Phase I awardees)

- Identifies other uses of technology
- Determines competitive advantages
- Develops market entry strategy

Commercialization Accelerator Program Larta, Inc. (Phase II awardees)

- “Menu” of technical assistance/training programs in:
  - Strategic/business planning
  - FDA requirements
  - Technology valuation
  - Manufacturing issues
  - Patent and licensing issues
- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting
Look Towards 2017!

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