2019 SBIR/STTR Funding & Commercialization- Arizona Regional Summit:

*Takin’ Care of Business*

UA Tech Park - Event Center
Tuesday, March 26, 2019

Robert Vinson
NIH SBIR/STTR Program Office,
Office of Extramural Research
https://sbir.nih.gov
New to SBIR/STTR?

SBIR/STTR Application Process Infographic

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

[Diagram: Steps include Confirm Your Small Business Meets Eligibility Requirements, Develop an Innovative Research Idea, Five Required Registrations: (Overview), SBIR Omnibus (PA-16-302), STTR Omnibus (PA-16-303), Targeted SBIR/STTR FOAs]

http://sbir.nih.gov/infographic
Congressionally Mandated Programs

**SET ASIDE**

**SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**
Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

- 3.2% (FY18)

**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

- .45% (FY18)
Approximate SBIR/STTR Budgets by Agency, FY2018

- **Department of Defense (DOD)**: $1.750B
- **Department of Health & Human Services (DHHS)**, including the National Institutes of Health (NIH)*: $1.088B
- **Department of Energy (DOE)**, including Advanced Research Projects Agency – Energy (ARPA-E): $280M
- **National Science Foundation (NSF)**: $202.4M
- **National Aeronautics and Space Administration (NASA)**: $198.0M

**Agencies with Only SBIR Programs**

- **Department of Agriculture (USDA)**: $27.0M
- **Department of Homeland Security (DHS)**: Science and Technology Directorate (S&T) & Countering Weapons of Mass Destruction Office (CWMD): $20.8M
- **Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) & National Institute of Standards and Technology (NIST)**: $14.2M
- **Department of Transportation (DOT)**: $8.5M
- **Department of Education (ED)**: $7.5M
- **Environmental Protection Agency (EPA)**: $4.2M

*DHHS also issues contracts

~ $3.6B in FY2018 across all agencies
<table>
<thead>
<tr>
<th>2019 Budget</th>
<th>SBIR</th>
<th>STTR</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH</td>
<td>$1B</td>
<td>$141M</td>
</tr>
<tr>
<td>CDC</td>
<td>~$12M</td>
<td>N/A</td>
</tr>
<tr>
<td>ACL (NIDILRR)</td>
<td>~$3M</td>
<td>N/A</td>
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<tr>
<td>FDA</td>
<td>~$1M</td>
<td>N/A</td>
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NIH SBIR/STTR Budget Allocations FY2019

3.20% SBIR $1B
0.45% STTR $141M
Total FY19 $1.141B
<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>2018</td>
<td>SBIR</td>
<td>Phase I</td>
<td>3,607</td>
<td>665</td>
<td>18.4%</td>
<td>$164,092,776</td>
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<tr>
<td>2018</td>
<td>SBIR</td>
<td>Fast Track</td>
<td>730</td>
<td>147</td>
<td>20.1%</td>
<td>$41,420,240</td>
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<tr>
<td>2018</td>
<td>SBIR</td>
<td>Total Phase II</td>
<td>619</td>
<td>258</td>
<td>41.7%</td>
<td>$214,967,591</td>
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<tr>
<td>2018</td>
<td>SBIR</td>
<td>Regular Phase II</td>
<td>531</td>
<td>224</td>
<td>42.2%</td>
<td>$176,948,384</td>
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<tr>
<td>2018</td>
<td>SBIR</td>
<td>Phase IIB</td>
<td>84</td>
<td>32</td>
<td>38.1%</td>
<td>$36,023,223</td>
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<tr>
<td>2018</td>
<td>STTR</td>
<td>Phase I</td>
<td>1,011</td>
<td>211</td>
<td>20.9%</td>
<td>$52,320,567</td>
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<td>2018</td>
<td>STTR</td>
<td>Fast Track</td>
<td>129</td>
<td>27</td>
<td>20.9%</td>
<td>$8,767,497</td>
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<tr>
<td>2018</td>
<td>STTR</td>
<td>Total Phase II</td>
<td>79</td>
<td>27</td>
<td>34.2%</td>
<td>$20,972,412</td>
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<tr>
<td>2018</td>
<td>STTR</td>
<td>Regular Phase II</td>
<td>78</td>
<td>27</td>
<td>34.6%</td>
<td>$20,972,412</td>
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<tr>
<td>2018</td>
<td>STTR</td>
<td>Phase IIB</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>$0</td>
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<tr>
<td>2018</td>
<td>FY TOTAL</td>
<td></td>
<td>6,177</td>
<td>1,337</td>
<td>21.6%</td>
<td>$504,146,584</td>
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</table>

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR 3-Phase Program

**Discovery**

**Phase I Feasibility Study**

**Budget Guide:** $150K for SBIR and STTR

**Project Period:** 6 months (SBIR); 1 year (STTR)

**Development**

**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/to FDA

Many, but not all, IC’s participate

Varies~$1M per year; up to 3 years

**Commercialization**

**Phase III Commercialization**

NIH, generally, not the “customer”

Consider partnering and exit strategy early
Mission

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.
No SBIR/STTR funding authority
• SBIR/STTR programs authorized through **FY22**
• 4 pilot programs extended through **FY22**
  o **SBIR Direct Phase II** (some by 1/7/19, rest by 4/5/19)
    ▪ Apply at Application Level for SBIR Direct Phase II (New)
    ▪ NIH Only, not available for STTR by law
  o **Commercialization Readiness Pilot Program** (SB1 or other options targeting 4/5/19)
  o **3% Agency SBIR Admin funds** (more outreach, more commercialization assistance, etc.)
  o **NIH Phase 0 Proof of Concept Centers** (REACH - planning)
• Increase Technical and Business Assistance
  o Up to $6,500 per year per Phase I (up from $5K/year)
  o Up to $50,000 per Phase II project (up from $5K/year)
  o Request at time of APPLICATION
  o Request in F. Other Direct Costs lines 8-10 on SBC budget
  o Label as “Technical Assistance”
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
Technical Assistance Programs

Niche Assessment Program - Foresight Science & Technology (Phase I Awardees)
https://sbir.nih.gov/nap

- Helps jump start commercialization efforts
- Determines competitive advantages
- Develops market entry strategy

Commercialization Accelerator Program - Larta, Inc. (Phase II Awardees)
https://sbir.nih.gov/cap

- Technical Assistance/Training in:
  - Strategic/business planning
  - FDA requirements
  - Technology evaluation
  - Manufacturing issues
  - Patent and licensing issues
- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting
Multi-IC Technology Development Programs
(open to eligible Awardees from participating ICs)

I-Corps™ at NIH
An intensive *Entrepreneurial Immersion* course for scientists

Facilitating Partnerships

12 Participating ICs + CDC
SBIR/STTR 3-Phase Program

**Feasibility Phase I**
- Discovery
- Feasibility
- Full R/D

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

**Competing Renewal Award Phase IIB**
- Only Some ICs Participate
- Congressional authority back!
- Re-implemented fall/winter

**Commercialization Phase III**
- Commercialization Readiness Pilot (CRP)
- $3M for up to 3 years
- Re-implemented winter/spring

Congressional authority back! Re-implemented fall/winter
SBIR/STTR Fast-Track

**Discovery Phase I**
- Feasibility

**Development Phase II**
- Full R/D
- **Fast-Track**
  - Direct to Phase II

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

**Commercialization Phase III**
- Additional R/D
  - 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
NIH
Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR
Direct to Phase II

Discovery
Phase I
Feasibility

Development
Phase II
Full R/D

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

Commercialization
Phase III
Additional R/D

Fast-Track

Phase I → Phase II

Direct to Phase II

• SBIR only
• Bypass Phase I grant
• Congressional authority is BACK!
Phase IIB Competing Renewal Award

- 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!
Funding Opportunities Announcements (FOAs)

a publicly available document by which a federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.

https://sbir.nih.gov/funding
# Omnibus vs Targeted FOAs

<table>
<thead>
<tr>
<th></th>
<th>Omnibus</th>
<th>Targeted</th>
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<tbody>
<tr>
<td><strong>Due Dates</strong></td>
<td>Standard Due Dates</td>
<td>Standard or Customized Due Dates</td>
</tr>
<tr>
<td><strong>Review</strong></td>
<td>SBIR/STTR panels at CSR</td>
<td>SBIR/STTR panels at CSR &lt;OR&gt; SBIR/STTR panel at IC</td>
</tr>
<tr>
<td><strong>Application</strong></td>
<td>Follow SF424 R&amp;R SBIR/STTR Application Guide &amp; Annotated Form Set</td>
<td>Follow SF424 R&amp;R SBIR/STTR Application Guide &amp; Annotated Form Set &lt;AND&gt; any additional instructions in FOA</td>
</tr>
</tbody>
</table>

**Read FOA very carefully!**
NIH, CDC, FDA, & SBIR/STTR Grant
Solicitation “Parent” FOAs:

Clinical Trial Not Allowed

SBIR: PA-18-574    STTR: PA-18-575

Clinical Trial Required

SBIR: PA-18-573    STTR: PA-18-576

Release: January 16, 2018
Standard Due Dates: April 5th, September 5th, January 5th
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
SBIR Contract Solicitation (NIH, CDC) - CLOSED
Closing Date: October 22, 2018  5:00PM EDT
Program Solicitation PHS 2019-1 (SBIR Only)

NIH Guide Notice: NOT-OD-18-209
NIH Guide for Grants and Contracts
Release: Weekly receipt dates specified in each FOA
Determine if Your Study is an NIH-defined Clinical Trial

Does your study…

1. Involve one or more human participants?
2. Prospectively assign human participant(s) to intervention(s)?
3. Intend to evaluate the effect of an intervention on human participants
4. Have a health-related biomedical or behavioral outcome?

If “yes” to ALL of these questions, your study is considered a clinical trial

Clinical Trial Interactive Decision Tree: https://grants.nih.gov/ct-decision/index.htm
Clinical Trial Requirements for Grants and Contracts

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Learn more

Your human subjects study may meet the NIH definition of a clinical trial.

https://grants.nih.gov/policy/clinical-trials.htm
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
Timeline: New Applications

Due Date | Scientific Review | Council Review | Award Date (earliest)
--- | --- | --- | ---
April 5th | May/June | Aug/Sept | October
Sept 5th | Oct/Nov | Jan/Feb | March
Jan. 5th | Feb/Mar | May/June | July
Review Criteria

Overall Impact Score:

Scored Review Criteria (score 1-9)
- Significance (Real Problem/Commercial Potential)
- Investigators (PI and team)
- Innovation (New or Improved?)
- Approach (Research Design, Feasible)
- Environment (Facilities/Resources)

Additional Review Criteria (not scored individually)
- Protection of Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards
Efforts in Diversity

Administrative Supplements to Promote Diversity in Research and Development Small Businesses-SBIR/STTR

NIH will now offer funding for SBIR/STTR awardees to recruit and compensate students, postdoctorates, and eligible investigators from underrepresented groups to participate in SBIR research projects.

Institutes/Centers Currently Participating

National Cancer Institute (NCI)
National Eye Institute (NEI)
National Human Genome Research Institute (NHGRI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute on Drug Abuse (NIDA)
National Institute of General Medical Sciences (NIGMS)
National Institute of Neurological Disorders and Stroke (NINDS)
National Institute of Nursing Research (NINR)
National Institute on Minority Health and Health Disparities (NIMHD)
National Center for Complementary and Integrative Health (NCCIH)
National Center for Advancing Translational Sciences (NCATS)
National Heart, Lung, and Blood Institute (NHLBI)

Lift Labs

• Develops new technologies to provide proactive care for people with essential tremor and Parkinson's Disease

• Acquired by Google in September 2014

Anupam Pathak, Ph.D.
Founder & CEO
NINDS SBIR Awardee

http://www.liftlabsdesign.com/
SenesTech

- Limits rodent fertility in a non-lethal and environmentally-friendly way
- Works with NYC Subway System, and Chicago Transit Authority

http://senestech.com/

Loretta Mayer, Ph.D.
Founder & CSO
NIEHS SBIR Awardee
“[SBIR] has been a long, trying, but worthwhile journey...from multiple submissions that were not discussed...to applications that scored below the funding levels...to concurrent applications (one Phase II and a Phase I) emerging from the rigorous peer review process with impact scores in the “Excellent" range.”

Laverne Morrow Carter, Ph.D.
Founder & President, REESSI
NIMHD SBIR Awardee

http://www.reessi.com
“As a native Spanish-speaking curriculum designer with a background in literary and performing arts, I work as a principal investigator on a number of NIH-funded projects. The SBIR and STTR programs allow me to translate evidence-based practices into web-based multimedia programs that offer skill-building tools for improving health and educational outcomes among Latino audiences.”
“Talk to a HHS Program Officer at least 6-8 weeks before a deadline for application specific advice.”

Click here for the list of HHS SBIR Program Managers

Not sure who to contact? Email sbir@od.nih.gov
SAVE THE DATE!
21st Annual HHS SBIR/STTR Conference

October 28 – October 30, 2019
Virginia Beach, VA

Stay connected for updates!
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Get Connected!

- Subscribe to the SBIR/STTR Listserv:
  - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: subscribe SBIR-STTR your name

- NIH Guide for Grants and Contracts (weekly notification)

- Follow us on Twitter: @NIHsbir

- Read our NIH SBIR/STTR Success Stories

- Connect with Us

- Email: sbir@od.nih.gov
Matthew Portnoy, PhD
NIH SBIR/STTR Program Coordinator
Phone: 301-435-2688
Email: mportnoy@mail.nih.gov

Robert Vinson
SBIR/STTR Program Manager
Phone: 301-435-2713
Email: robert.vinson@nih.gov

JP Kim, JD, MBA, MSc
SBIR/STTR Program Manager
Phone: 301-435-0189
Email: jpkim@nih.gov

Julie Beaver, MD, MS
SBIR/STTR Statistician
Phone: 301-496-8807
Email: julie.beaver@nih.gov

Patricia Swayne
SBIR/STTR Communications Specialist
Phone: 301-402-1632
Email: patricia.swayne@nih.gov