



HHS SBIR/STTR PHS 2017-2 GRANT OMNIBUS WEBINAR

Thursday June 29, 2017

2:00-3:30PM

Matthew Portnoy, Ph.D.

SBIR/STTR Program Coordinator

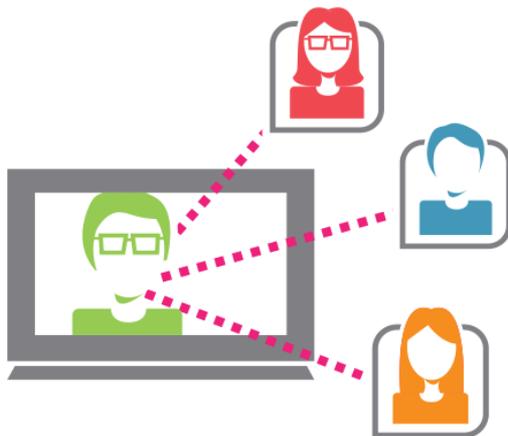
Director of the Division of Special Programs

Office of Extramural Research, NIH



AGENDA

- Introductions
- Reauthorizations
- SBIR 101
- New Omnibus Solicitations
- 2017 Deadlines
- Questions & Answers
- Closing



NIH

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

SAVE THE DATE!

November 7-9, 2017

Milwaukee, Wisconsin

19TH ANNUAL HHS SBIR/STTR CONFERENCE
In the Heartland of Biohealth Innovation

Digital Health

Medical Device & Diagnostics

Integrated Health Solutions

Health Research Institutes

Biotech & BioPharma

ADVANCING HEALTH THROUGH RESEARCH AND DISCOVERY
CTSI

November 7-9
Milwaukee, WI

DEPARTMENT OF HEALTH & HUMAN SERVICES - USA

<https://ctsi.mcw.edu/event/nih-sbir-milwaukee-2017/>



<https://sbir.nih.gov>



What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, also known as America's Seed Fund, are one of the largest sources of early-stage capital for technology commercialization in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization.

In Fiscal Year 2017, 101% SBIR and STTR programs will invest over 325 million dollars into health and life science companies that are creating innovative technologies that align with NIH's mission to improve health and save lives. A key objective is to translate promising technologies to the private sector and enable the ensuing innovations to...

NIH SBIR/STTR COMPANION PROGRAMS

NEWS

Registration Open for the 13th Annual Health and Human Services SBIR/STTR Conference in the heartland of Biotech Innovation - Indianapolis, IN
JUNE 8, 2017

Just Released - 2017 HHS SBIR and STTR Finalist Award Submissions





What are SBIR and STTR Programs?

SBIR

The NIH SBIR program funds early stage small businesses that are seeking to commercialize innovative biomedical technologies. This competitive program helps small businesses participate in federal research and development, develop life-saving technologies, and create jobs.

STTR

The NIH STTR program is similar to the NIH SBIR program, but requires that the small business formally collaborate with a research institution in Phase I and Phase II. Learn more [about](#) the NIH SBIR and STTR programs, including their [critical differences](#).

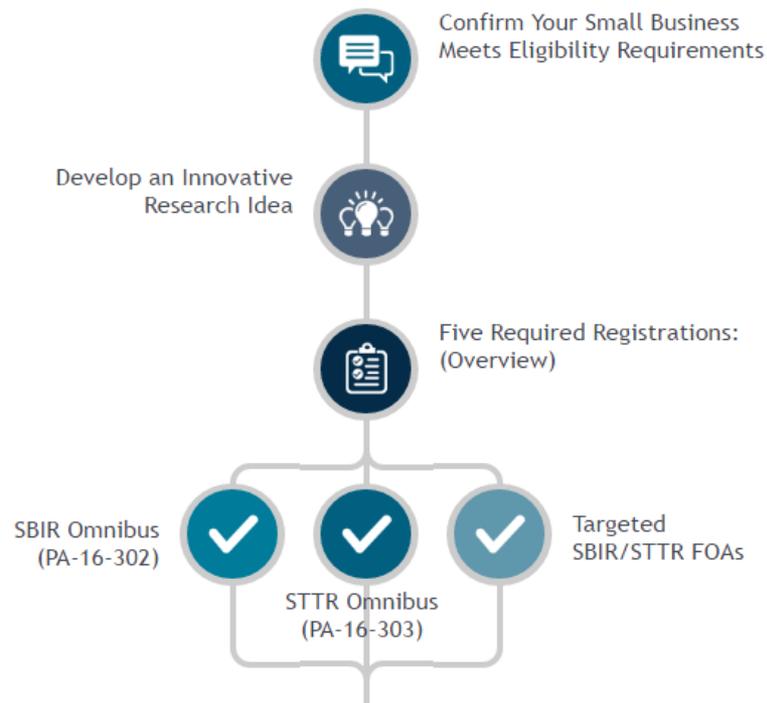
<https://sbir.nih.gov>



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.

START THE SBIR/STTR
APPLICATION PROCESS
INFOGRAPHIC



<http://sbir.nih.gov/infographic>



SET ASIDE



(FY17)

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

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



(FY17)

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





- 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. 114-328 Re-Authorizes program through FY2022





- 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. 114-328 Re-Authorizes program through FY2022





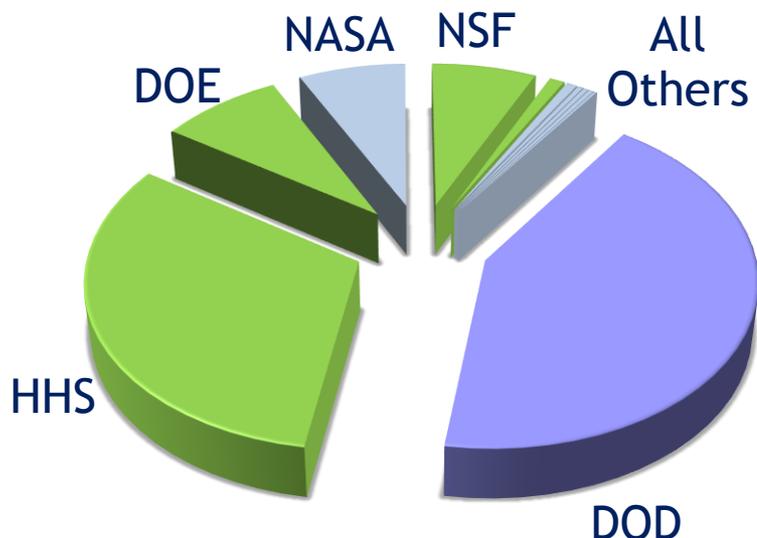
- Congress passed a 5 year SBIR/STTR Reauthorization as part of S.2943, the 2017 National Defense Authorization Act (NDAA)
- SBIR/STTR programs reauthorized for 5 year FY18 through FY22
- Simple, one line reauthorization
- No pilot programs extended, all expire 9/30/17
 - Direct Phase II
 - CRP
 - 3% Agency SBIR Admin funds
 - NIH Phase 0 Proof of Concept Centers
- Bills circulating in Congress as we speak on these and other areas. - Stay tuned.





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

SBIR/STTR Budgets by Agency FY15



**~ \$2.5B in FY2015
across all agencies**



Agencies with SBIR and STTR Programs	Budget
Department of Defense (DOD)	\$1.070B
Department of Health and Human Services (HHS), including the National Institutes of Health (NIH)*	\$797.0M
Department of Energy (DOE), including Advanced Research Projects Agency - Energy (ARPA-E)	\$206.1M
National Aeronautics and Space Administration (NASA)	\$180.1M
National Science Foundation (NSF)	\$176.0M
Agencies with SBIR Programs	Budget
U.S. Department of Agriculture (USDA)	\$25.3M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) and Domestic Nuclear Detection Office (DNDO)	\$17.7M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)*	\$8.4M
Department of Transportation (DOT)	\$7.9M
Department of Education (ED)	\$7.5M
Environmental Protection Agency (EPA)	\$4.2M

2017 Budget	SBIR	STTR
NIH	\$861M	\$121M
CDC	~\$11.0M	N/A
ACL (NIDILRR)	~\$3M	N/A
FDA	~\$1M	N/A



- 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:
 - Greater than 50% US-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 (For FOAs after 1/28/2013 NIH; 7/10/14 CDC)

Determined at Time of Award





- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
 - Minimum 40% by small business
 - Minimum 30% by US research institution
- US 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





Discovery

Phase
I

Phase I Feasibility Study

Budget Guide: \$150K for SBIR and STTR

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



Development

Phase
II

Phase II Full Research/R&D

\$1M for SBIR and STTR, over two years

Phase
IIB

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

Phase III Commercialization

NIH, generally, not the “customer”

Consider partnering and exit strategy early



	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g. university)
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

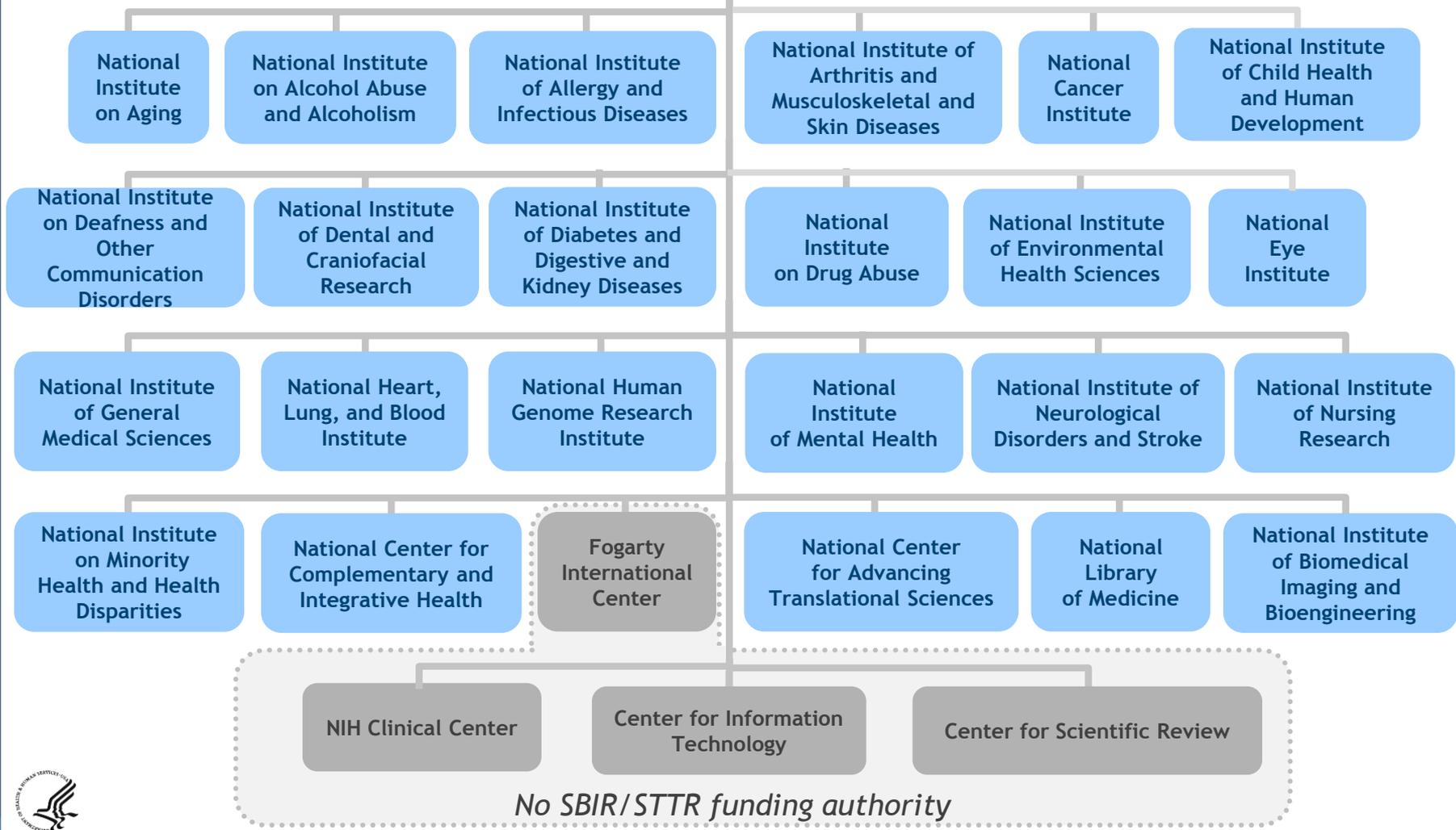
Award is always made to the small business



Office of Research Infrastructure Programs

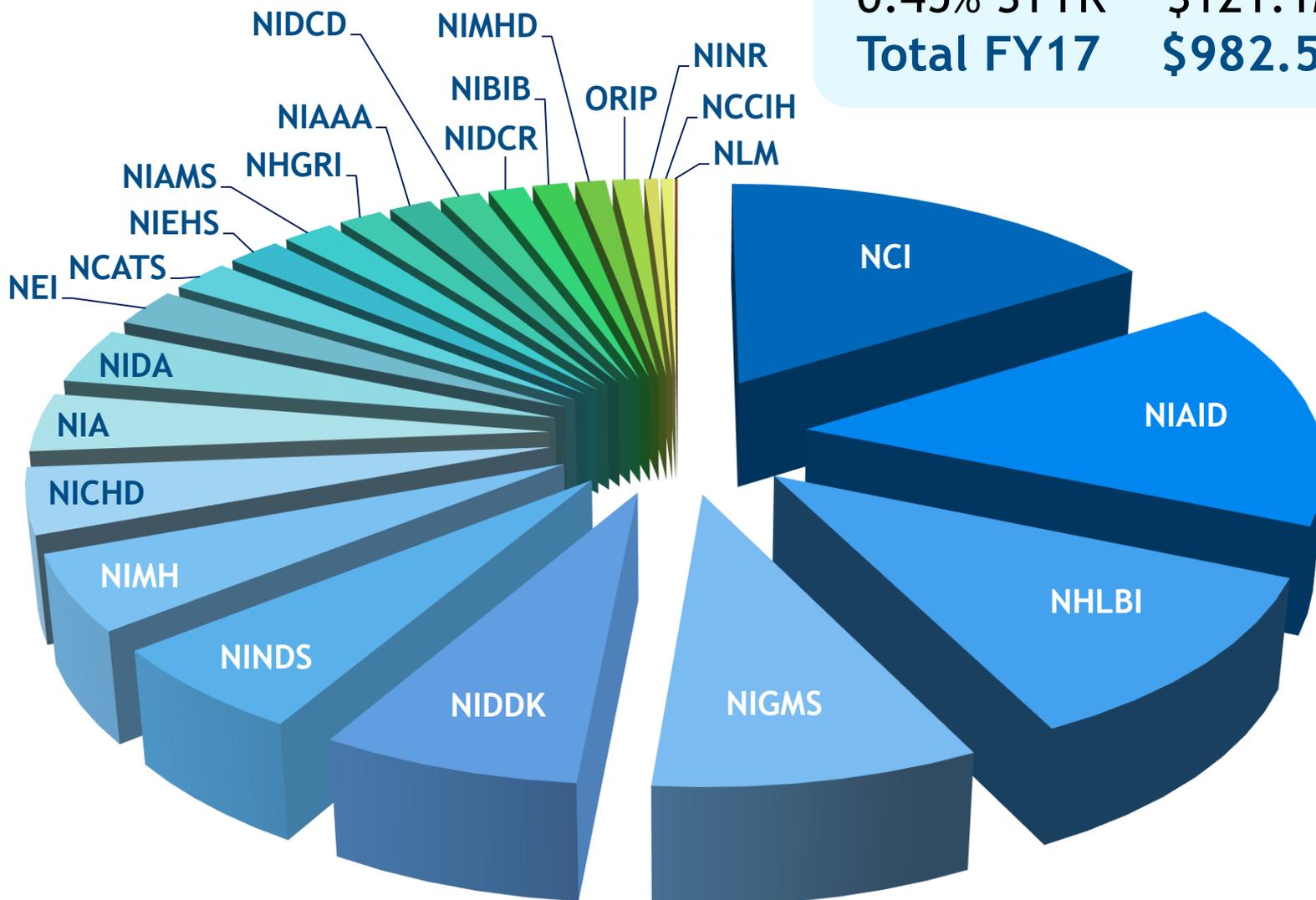
Office of the Director

<http://www.nih.gov/icd>



NIH SBIR/STTR Budget Allocations FY2017

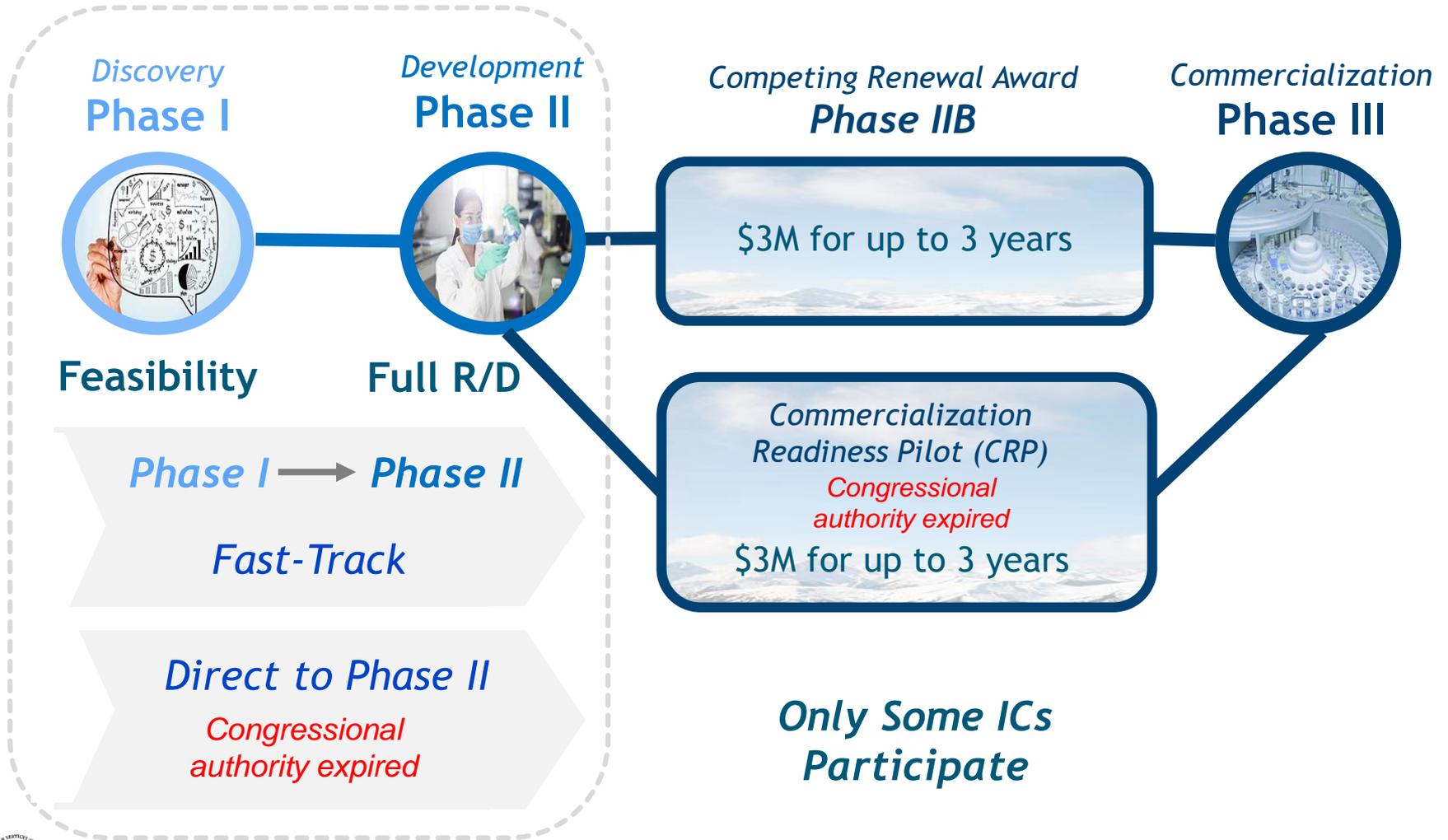
3.2% SBIR	\$861.4M
0.45% STTR	\$121.1M
Total FY17	\$982.5M

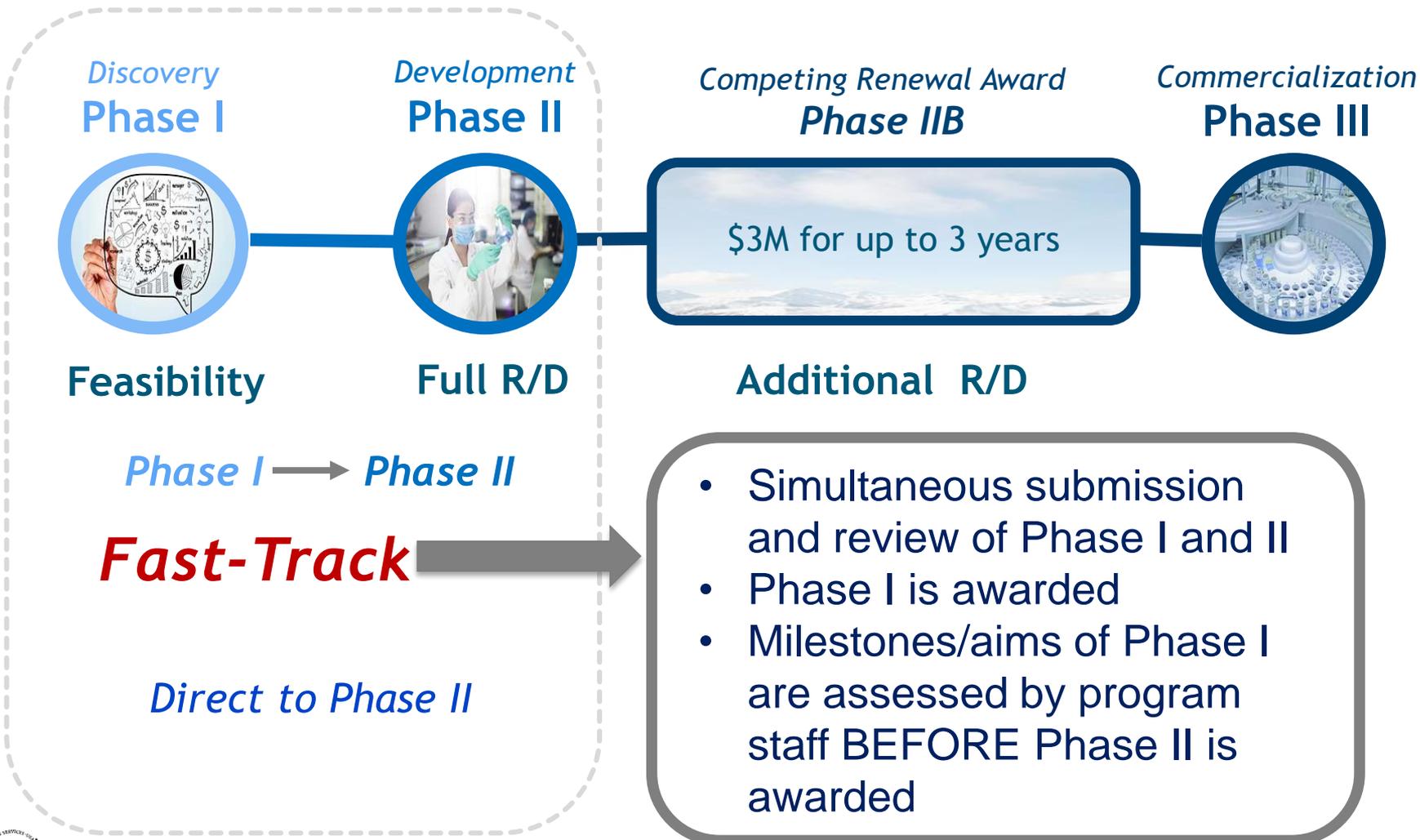


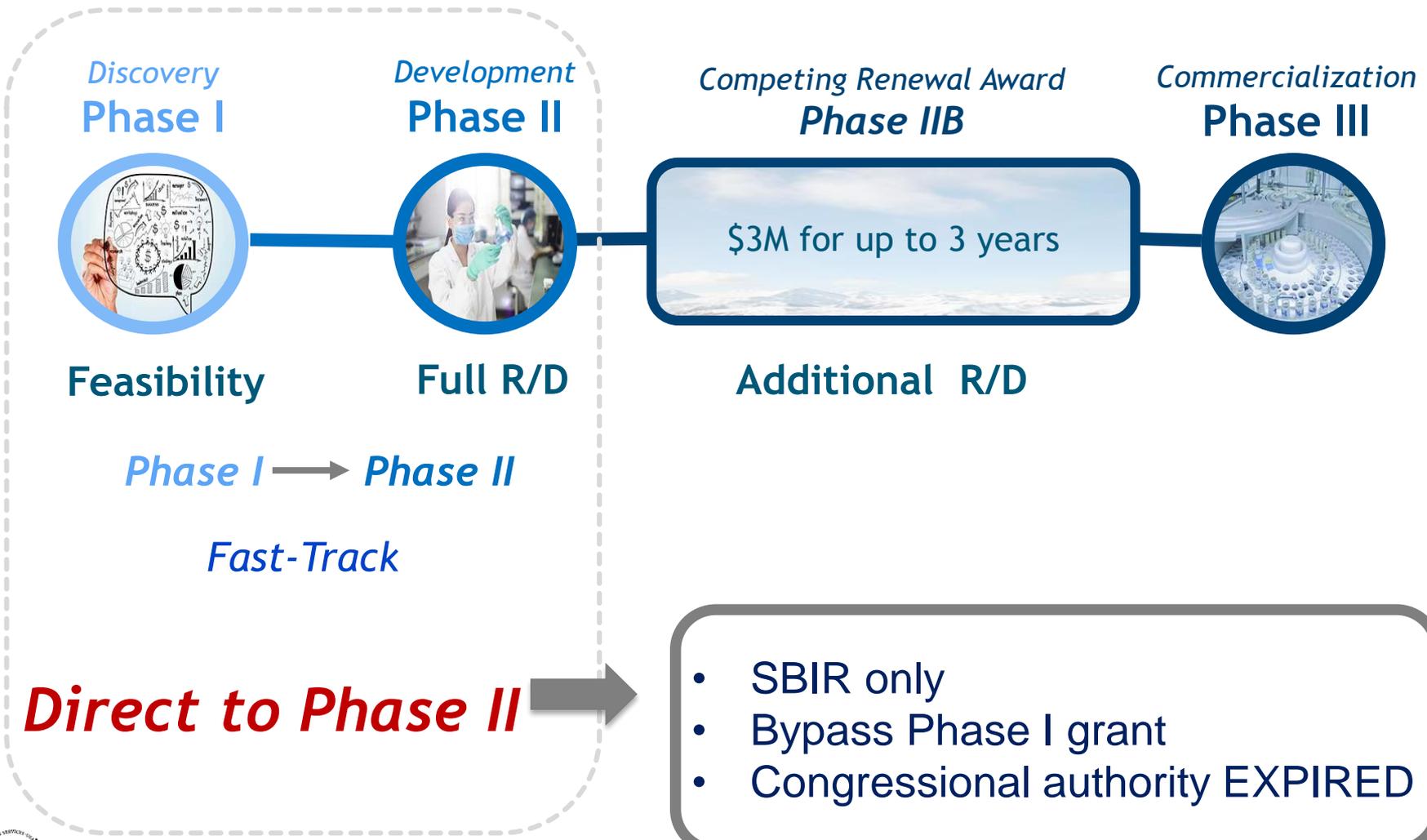


Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

NIH SBIR/STTR 3-Phase Program







Discovery
Phase IDevelopment
Phase II**Competing Renewal
Phase IIB****\$3M for up to 3 years**Commercialization
Phase III

- 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.

2017 SBIR and STTR Omnibus Grant Solicitations for the NIH, CDC, and FDA

- SBIR Omnibus Funding Opportunity Announcement (PA-17-302)
 - STTR Omnibus Funding Opportunity Announcement (PA-17-303)
 - 2017 Program Descriptions and Research Topics Document
 (1.6 MB)  (479 KB)
 - 2017 SBA approved topics list for budget waivers
 (1.6 MB)  (479 KB)
-  NIH SBIR/STTR Grant Forms

Standard Due Dates:

-  January 5
-  April 5
-  September 5

NIH SBIR Direct to Phase II Pilot Solicitation/s

The Congressional authority for SBIR Direct Phase II has expired.

Standard Due Dates:

-  January 5
-  April 5
-  September 5

Targeted SBIR/STTR Solicitations

See individual SBIR/STTR targeted solicitations

Due dates vary.
See individual announcements for dates.

[Top of Page](#)

<https://sbir.nih.gov/funding>



	Omnibus	Targeted
Due Dates	Standard Due Dates	Standard or Customized Due Dates
Review	SBIR/STTR panels at CSR	SBIR/STTR panels at CSR <OR> SBIR/STTR panel at IC
Application Instructions	Follow SF424 R&R SBIR/STTR Application Guide & Annotated Form Set	Follow SF424 R&R SBIR/STTR Application Guide & Annotated Form Set <AND> any additional instructions in FOA

Read FOA very carefully!





- NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation
“Parent” FOAs: **SBIR: PA-17-302** **STTR: PA-17-303**

Release: June 5, 2017

Standard Due Dates: September 5th, January 5th

- These FOAs are being issued with limited due dates to accommodate the transition from FORMS-D to FORMS-E application packages.
 - **HHS expects to re-issue these Omnibus after the January 5, 2018 due date.**
- SBIR Contract Solicitation (NIH, CDC) - Program Solicitation **PHS 2017-2** (SBIR Only)
NIH Guide Notice **NOT-OD-17-070**
Release: PHS 2018-1...soon
 - **NIH Guide for Grants and Contracts**
Release: Weekly receipt dates specified in each FOA





- National Eye Institute (NEI)
- National Human Genome Research Institute (NHGRI)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Library of Medicine (NLM)
- National Center for Advancing Translational Sciences (NCATS)
- Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)
- U.S. Food and Drug Administration (FDA)
- If your proposed work includes an NIH-defined clinical trial that would be assigned to one of these NIH Institutes/Centers, you should contact relevant program staff to discuss alternatives for support of those studies.





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

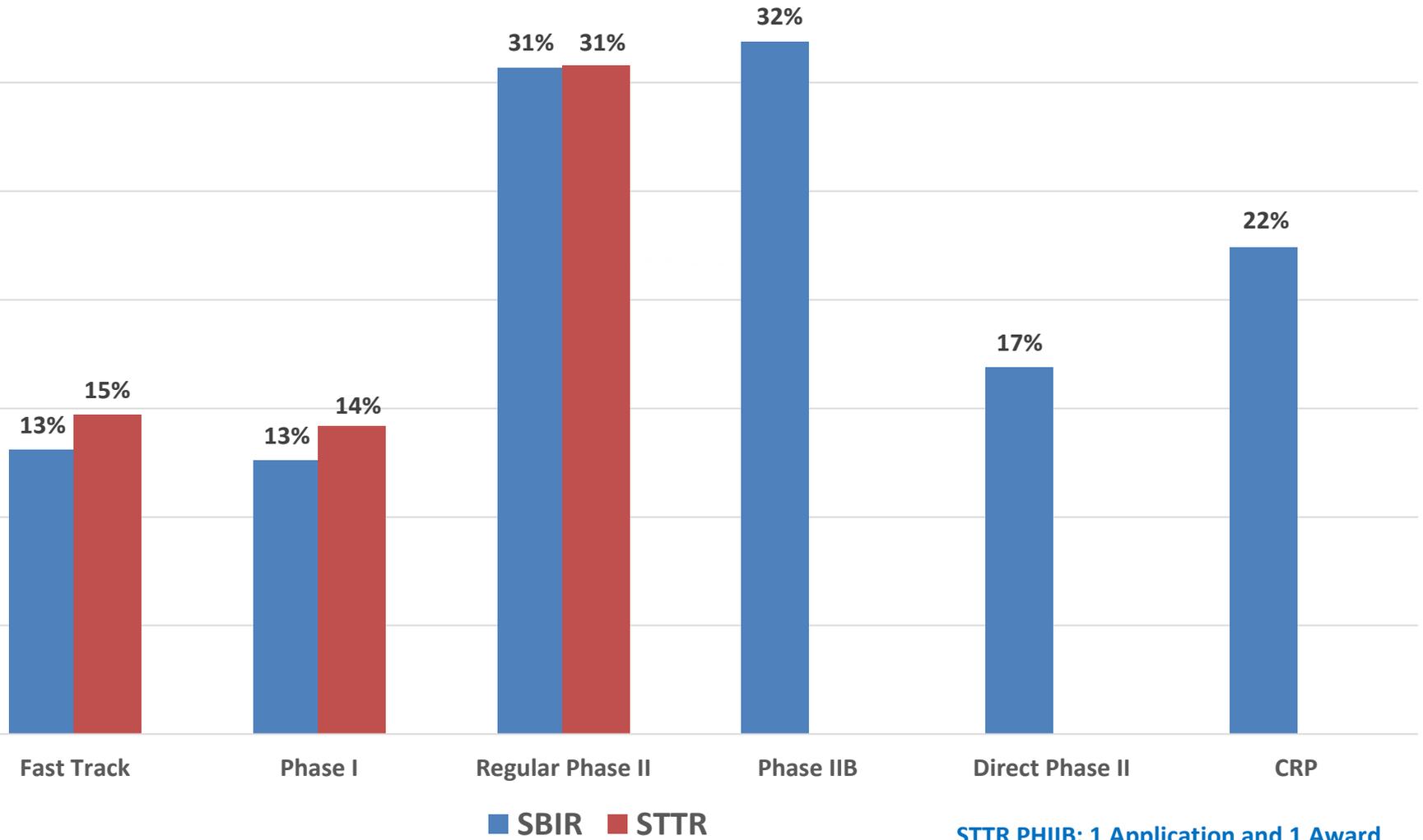
- Research projects related to the NIH mission
- “Other” areas of research within the mission of an awarding component

Keyword Search the Solicitation
Ctrl + F



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

NIH 2016 SBIR/STTR Grants Success Rate by Phase



STTR PHIB: 1 Application and 1 Award





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/>



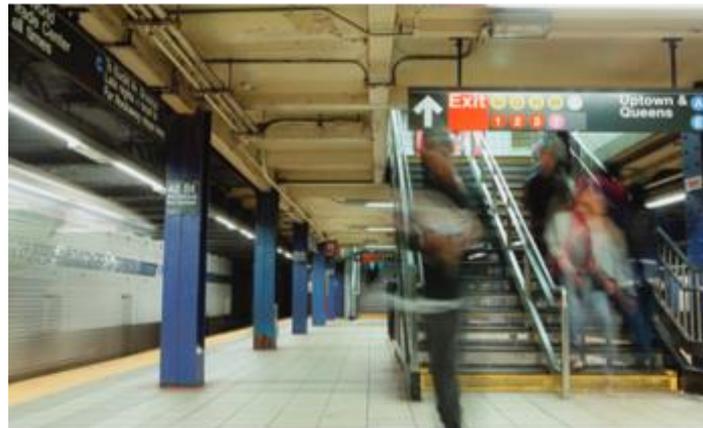


SenesTech

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



Loretta Mayer, Ph.D.
Founder & CSO
NIEHS SBIR Awardee



<http://senestech.com/>



Be Prepared to Resubmit!



“[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.”



Jessie Marquez

Instructional Designer at
IRIS Educational Media

<http://www.irised.com/>



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



Excerpt from single-project FOA in NIH Guide...

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

3. Go to [Grants.gov](https://www.grants.gov) to download an application package to complete the application forms offline or create a Workspace to complete the forms online; submit your application to Grants.gov, and track your application in eRA Commons.

Learn more about the various submission options.

U.S. Department of Health & Human Services

Application Submission System & Interface
for Submission Tracking (ASSIST)

Submit multi-project grant applications electronically to NIH and other Public Health Service Agencies...

GRANTS.GOV

VIEW GRANT OPPORTUNITY

PA-13-304
NIH Small Research Grant Program (Parent R03)
Department of Health and Human Services
National Institutes of Health

Selected Grant Applications for Download

Download the application and its instructions by selecting the corresponding download link. You will then be able to save the files on your computer for future reference and use.

READ BELOW BEFORE YOU APPLY FOR THIS GRANT!
Before you can view and complete an application package, you MUST have Adobe Reader installed. Application packages are posted in Adobe Reader format. You may receive a validation error using incompatible versions of Adobe Reader. To prevent a validation error, it is now recommended you uninstall any earlier versions of Adobe Reader and install the latest compatible version of Adobe Reader. If more than one person is working on the application package, ALL applicants must be using the same software version. Click for more information on Adobe Reader Compatibility.

Please click the support tab for additional resources.

Below is a list of the application(s) currently available for the Funding Opportunity.

CFDA	Competition ID	Competition Title	Open Date	Close Date	Actions
	FORMS-C	Forms-C	08/07/2013	08/07/2016	Select Application Package to Download





Applicant initiates research idea



Small Business Concern confirms Eligibility



Submits SBIR/STTR grant application to NIH electronically



NIH Center for Scientific Review assigns to IC and IRG

1-2 Months



IC staff prepare funding plan for IC Director



Advisory Council or Board recommend Approval

3 Months



Scientific Review Group evaluates scientific merit

2-4 Months



IC allocates funds



Grantee conducts research



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





Talk to a HHS Program Officer at least a month before a deadline for application specific advice.

The screenshot shows the NIH SBIR/STTR website. A navigation menu on the left includes: REVIEW, POLICY, TECHNICAL ASSISTANCE, RESOURCES, STATISTICS AND SUCCESS, and ENGAGE AND CONNECT. A dropdown menu is open over the 'ENGAGE AND CONNECT' section, showing 'Contact' and 'Engage' options. The 'Contact' dropdown lists: Contact SBIR/STTR, IC Program Contacts, eRA Service (IC Program Contacts submission Qs), and Connect. The 'Engage' dropdown lists: Twitter, Listserv, News, Webinar, and Events. Below the dropdown, a table lists program contacts for various NIH institutes.

Financial/Grants Mgmt Contact	
<p>Ms. Linda Whipp Phone: 301-496-1472 Fax: 301-402-3672 Email: Linda.Whipp@nih.gov</p>	<p>Ms. Judy Fox Phone: 301-443-4704 Fax: 301-443-3891 Email: Judy.Fox@nih.gov</p>
<p>Ms. Vandhana Khurana, MBA Phone: 240-669-2966 Fax: 301-493-0597 Email: khuranav@niaid.nih.gov</p>	<p>Jason Lundgren Phone: 240-669-2973 Fax: 301-493-0597 Email: Jason.Lundgren@nih.gov</p>

Click here for the list of HHS SBIR Program Managers
Not sure who to contact? Email sbir@od.nih.gov





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](#)





- SBIR/STTR award budget HARD caps in place
- Pre-approved topics list can be found on funding page:
<https://sbir.nih.gov/funding>

Award Guidelines

Program	Phase I	Phase II
SBIR	\$150,000	\$1,000,000
STTR	\$150,000	\$1,000,000

Award Hard Caps - cannot exceed

Program	Phase I	Phase II
SBIR	\$225,000	\$1,500,000
STTR	\$225,000	\$1,500,000



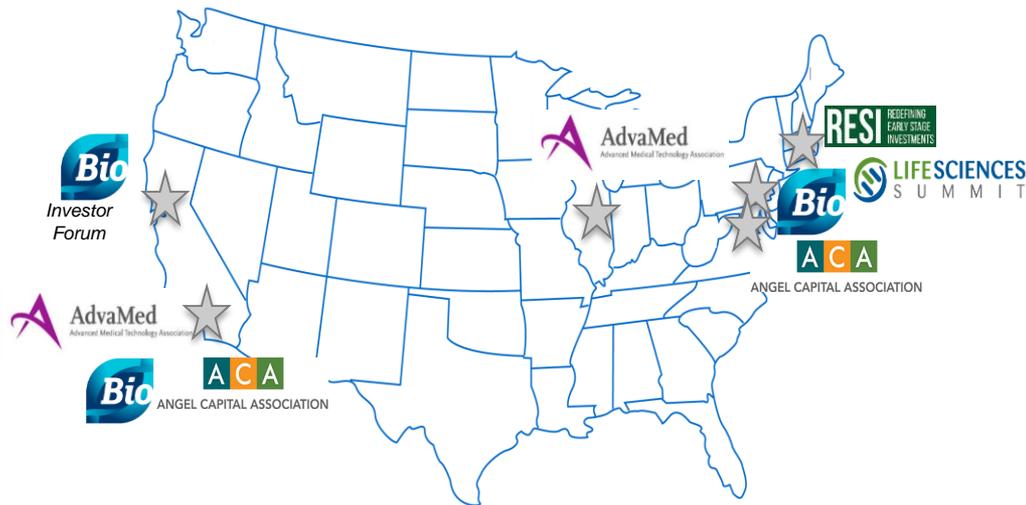
I-Corps™ at NIH

An intensive *Entrepreneurial Immersion* course for scientists



12 Participating ICs + CDC

Facilitating Partnerships





Niche Assessment Program-Foresight S&T

(Phase I Awardees)

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



Commercialization Accelerator Program - Larta, Inc.

(Phase II Awardees)

- 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





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](https://twitter.com/NIHsbir)
- Read our [NIH SBIR/STTR Success Stories](#)
- [Connect with Us](#)
- Email: sbir@od.nih.gov





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



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*SBIR/STTR Communications
Specialist*

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Email: patricia.swayne@nih.gov





- Is it required to have a company to apply?
- Will SBIR Direct Phase II return, why did it go away?
- Are there significant technical changes to the Omnibus solicitation since the last round?
- How long is approval process assuming everything is submitted correctly?
- Is there any special preference for Socially or Economically Disadvantaged- or Minority-owned Small Business?
- We are planning a fast track submission for Sept 5 deadline, can you tell us more about it?
- What is the easiest way to submit through grants.gov or using NIH assist? Are updates allowed after submission?
- I would like to know the importance of preliminary results. Our project is in it's infancy. We have proof of concept in the literature, but our proposal is far more extensive and risky than what has been demonstrated in the literature.
- What helps to ensure a qualifying score. What are reviewers looking for in a submission? Does academic partnership increase the odds of funding?
- Do we need to apply through a specific branch of the NIH?
- Interested in CDC/NIOSH and NIEHS RFPs, and whether multiple grants of different topics can be applied in the same grant cycle.
- If an application is submitted to a specific FOA in phase 1, can it be renewed and submitted to another FOA for phase 2?
- Do I need an indirect cost rate agreement before applying for sbir grants?



NIH

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Milwaukee, Wisconsin

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In the Heartland of Biohealth Innovation

Digital Health

Medical Device & Diagnostics

Integrated Health Solutions

Health Research Institutes

Biotech & BioPharma

ADVANCING HEALTH THROUGH RESEARCH AND DISCOVERY
CTSI

November 7-9
Milwaukee, WI

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA

<https://ctsi.mcw.edu/event/nih-sbir-milwaukee-2017/>
Early Bird Registration ends Sept. 28!

