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

SBIR/STTR Programs: What University TT Staff Should Know About Accessing Over $3.6 Billion

AUTM Webinar Series
August 20, 2019 | 12:00pm-1:30pm EDT

The NIH SBIR/STTR Programs
By the National Institutes of Health (NIH), HHS

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

Your NIH Presenters

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

Learning Objectives

- An overview of the over $3.6 billion Federal-wide and over $1 billion HHS/NIH-wide SBIR and STTR programs.
- How to engage and collaborate with SBIR- and STTR-funded small businesses to leverage these opportunities.

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Learning Objectives

- Highlighting the value-added guidance a technology manager could provide his/her Institution and PIs/researchers as to how to tap into this $3.6 billion set aside and to help facilitate successful university-small business collaborations/opportunities under the SBIR and STTR programs.

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Aren't SBIRs just for small businesses? How much of this funding is available to nonprofit research institutions?

- $3.6 billion set aside across all Federal agencies for SBIRs & STTRs
  - Over $1 billion HHS/NIH set aside
- SBIRs
  - Small business must do at least 2/3 of the work (up to 33% budget available)
- STTR
  - Small business must do at least 40% of the work (up to 60% budget available)

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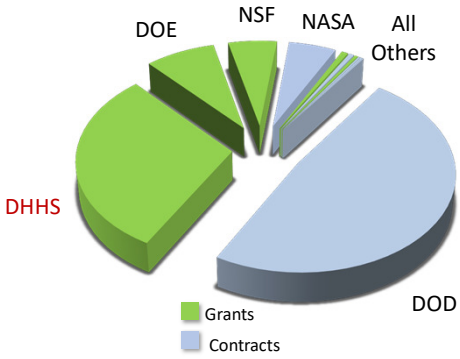
Providing Your Institution and its PIs/Researchers with an Overview of the SBIR and STTR Programs

SBIR/STTR Budgets by U.S. Agency, FY2018



~ $3.6 Billion in FY2018 across all agencies

SBIR·STTR America's Seed Fund

5 AGENCIES WITH SBIR & STTR PROGRAMS	APPROX BUDGET
Department of Defense (DOD)	$ 1.750 B
Department of Health and Human Services (DHHS), including the National Institutes of Health (NIH)*	**$1.088 B**
Department of Energy (DOE), including Advanced Research Projects Agency – Energy (ARPA-E)	$291.7M
National Science Foundation (NSF)	$ 202.4 M
National Aeronautics and Space Administration (NASA)	$198.0 M
6 AGENCIES WITH ONLY SBIR PROGRAMS	**APPROX BUDGET**
Department of Agriculture (USDA)	$27.0M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) & Countering Weapons of Mass Destruction Office (CWMD)	$20.8 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) & National Institute of Standards and Technology (NIST)	$14.2M
Department of Transportation (DOT)	$8.5 M
Department of Education (ED)	$7.5 M
Environmental Protection Agency (EPA)	$4.2 M

**DHHS also issues contracts*

NIH *Small Business Innovation Research (SBIR)*
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Mission of the SBIR and STTR Programs

To support scientific excellence and technological innovation by providing investment of Federal R&D funds into small businesses to work on critical national priorities and build a stronger economy.

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Congressionally Mandated Programs

SET ASIDE

3.2%

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

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

.45%

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

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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. 114-328 Re-Authorizes program through FY2022

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STTR Purpose and Goals

- 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

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Program 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:
  - 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, an Indian tribe, ANC or NHO (or a wholly owned business entity of such tribe, ANC or NHO), 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 some agencies)

Determined at Time of Award

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STTR Eligibility Criteria

- 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

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NIH SBIR/STTR 3-Phase Program

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

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SBIR and STTR Critical Differences

	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

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SBIR/STTR Reauthorization update

- SBIR/STTR programs reauthorized for 5 year FY18 through FY22
- Pilot programs extended through 2022
  - SBIR Direct Phase II
  - Commercialization Readiness Pilot (CRP) Programs
  - 3% Agency SBIR Admin funds
  - NIH Phase 0 Proof of Concept Centers
- Expand Technical Assistance
  - Phase I $6,500/year (up from $5,000/year)
  - Phase II $50,000/**project** (up from $5,000/year)
  - SBC hire own vendor or use agency vendor

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SBIR/STTR Legislative Update

- Increase Technical And Business Assistance (TABA)
  - Up to $6,500 per year per Phase I (up from $5K/year)
  - Up to $50,000 per Phase II project (up from $5K/year)
  - Request at time of APPLICATION
  - Request in "F. Other Direct Costs" lines 8-10 on SBC budget Label as "Technical Assistance"

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8.	
9.	
10.	
Total Other Direct Costs	

Subaward/Consortium/Contractual Costs are not pre-populated. Include both Direct and Indirect costs.

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Some of our Home Runs

23andMe illumina enchroma. sonicare

Biogen Symantec QUALCOMM INTUITIVE SURGICAL

www.sbir.gov/news/success-stories

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NIH 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.***

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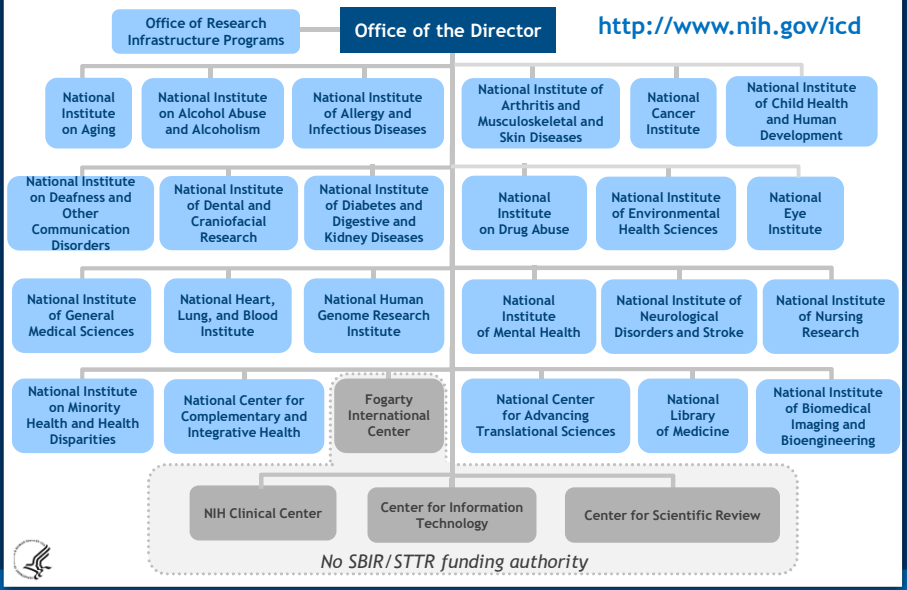
National Institutes of Health



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Where can my Institution and its PIs/Researchers learn more about the NIH SBIR and STTR programs?

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NIH SBIR/STTR Website

https://sbir.nih.gov

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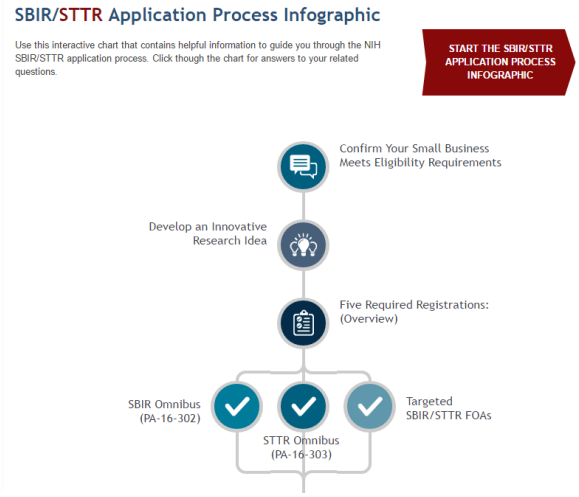
New to SBIR/STTR?



http://sbir.nih.gov/infographic

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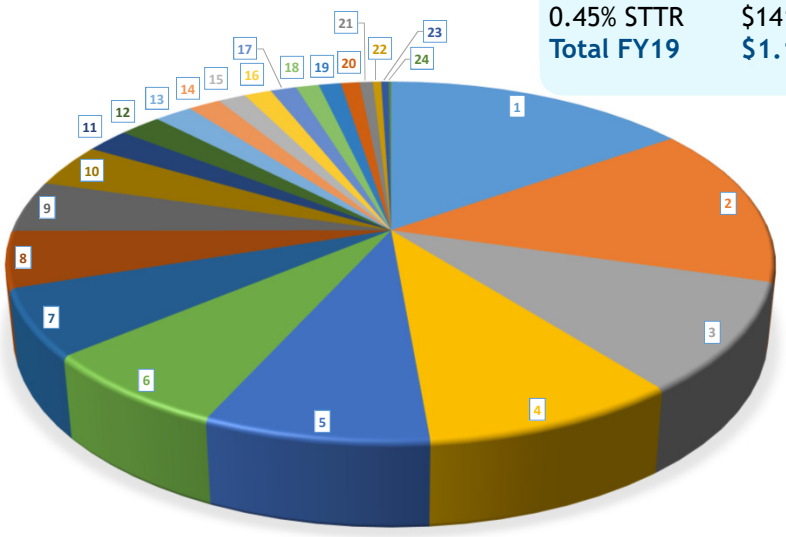
HHS Program Funding

2019 Budget	SBIR	STTR
NIH	$1B	$141M
CDC	~$12M	N/A
ACL (NIDILRR)	~$3M	N/A
FDA	~$1M	N/A

NIH SBIR/STTR Budget Allocations FY2019

3.2% SBIR	$1B
0.45% STTR	$141M
Total FY19	$1.145B



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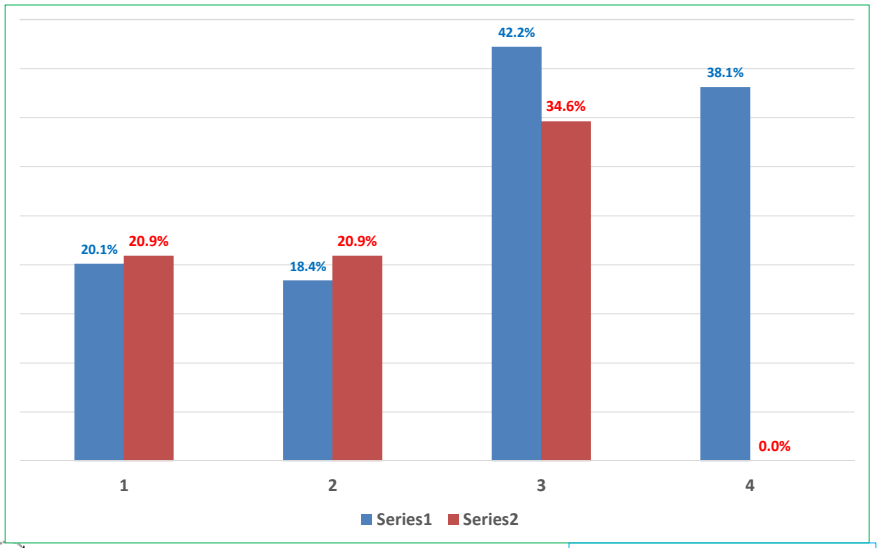
NIH SBIR/STTR 2018 Success Rate by Phase



Note: STTR Ph2B 1 application, no award.

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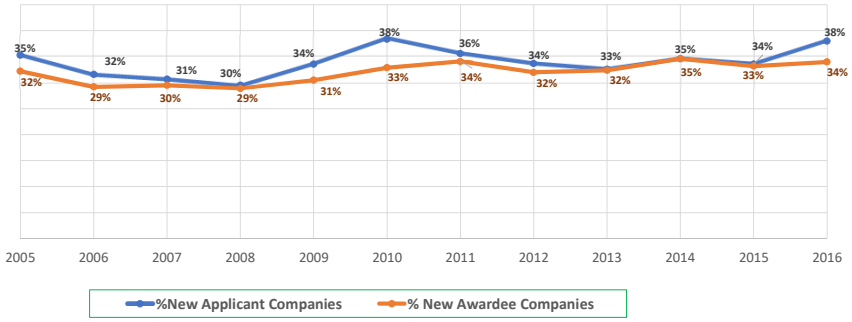
First Time Applications & Awards for SBIR/STTR

Percentage of New Applicant Companies and New Awardee Companies



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NIH SBIR/STTR 3-Phase Program

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Phase I → *Phase II*

Fast-Track

Direct to Phase II

Congressional authority back!
Re-implemented.

Competing Renewal Award
Phase IIB

Commercialization
Phase III

Commercialization Readiness Pilot (CRP)
Congressional authority back!
Re-implemented fall/winter
$3M for up to 3 years

Only Some ICs Participate

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How does my Institution and its PI/Researchers learn about SBIR/STTR funding opportunities and interests?

- Research the NIH IC websites
- Review Funding Opportunity Announcements (FOA)
  - Subscribe to the NIH Guide
- Subscribe to the NIH SBIR Listserv
- Research NIH Reporter (http://projectreporter.nih.gov)

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NIH SBIR/STTR FOAs

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

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Solicitations and Due Dates

NIH, CDC, & FDA SBIR/STTR Grant Solicitation "Parent" FOAs:

Clinical Trial Required

SBIR: PA-19-273 **STTR:** PA-19-271

Clinical Trial Not Allowed

SBIR: PA-19-272 **STTR:** PA-19-270

Release: May 7, 2019
Standard Due Dates: September 5th 2019, January 5th 2020, April 5th 2019.

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Solicitations and Due Dates

Specific FOAs: https://sbir.nih.gov/funding

- May offer additional resources in addition to funding
- Not all of them have specific set-asides or even separate reviews
- Not all Institutes/Centers Participate
- Example: NINDS only accepts clinical trials through specific FOAs
- Read program announcements carefully

Contact program staff at the end of the FOA

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Example Targeted FOAs

NINDS Cooperative Translational Programs

Small Molecules (PAR-18-546; PAR-18-541)

- Small molecule drug discovery and development
- Access to consultants and contracts that provide discovery, preclinical development, and clinical trial support
- Charles Cywin (charles.cywin@nih.gov)

Biologics (PAR-17-456; PAR-17-457; PAR-18-542; PAR-18-543)

- Therapeutic Biotechnology Products and Biologics (e.g. peptides, proteins, oligonucleotides, gene therapies, and cell therapies) discovery and development
- Access to consultants (statistics, regulatory, CMC)
- Chris Boshoff (chris.boshoff@nih.gov)

Neural Devices (RFA-NS-18-011; RFA-NS-18-012)

- Development, validation and verification, and early clinical studies of therapeutic and diagnostic devices
- Support for small clinical trial to collect safety & effectiveness data
- Nick Langhals (nick.langhals@nih.gov)

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More Information

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

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How do Small Business Concerns (SBCs) apply for SBIR and STTR funding?

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Electronic Submission

SBIR/STTR grant applications **and** SBIR contract proposals must be submitted **electronically**. Start 6-8 weeks before the application due date.

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

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Submit via ASSIST or Workspace

ASSIST

NIH's web-based service for the preparation, submission and tracking of grant applications.

Learn more about preparing your application using **ASSIST**

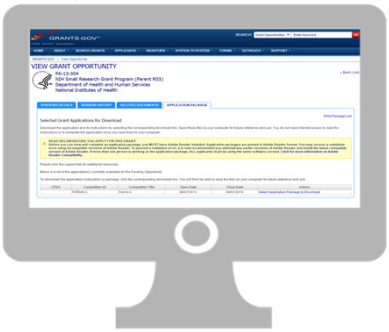
Grants.gov Workspace

A shared, online environment managed by Grants.gov where multiple users may simultaneously work on different forms within an application package.

Learn more about preparing your application using Grants.gov Workspace

Institutional Solutions (System-to-System, S2S)

Institution's own system to prepare and submit application data to Grants.gov complying with all application requirements.



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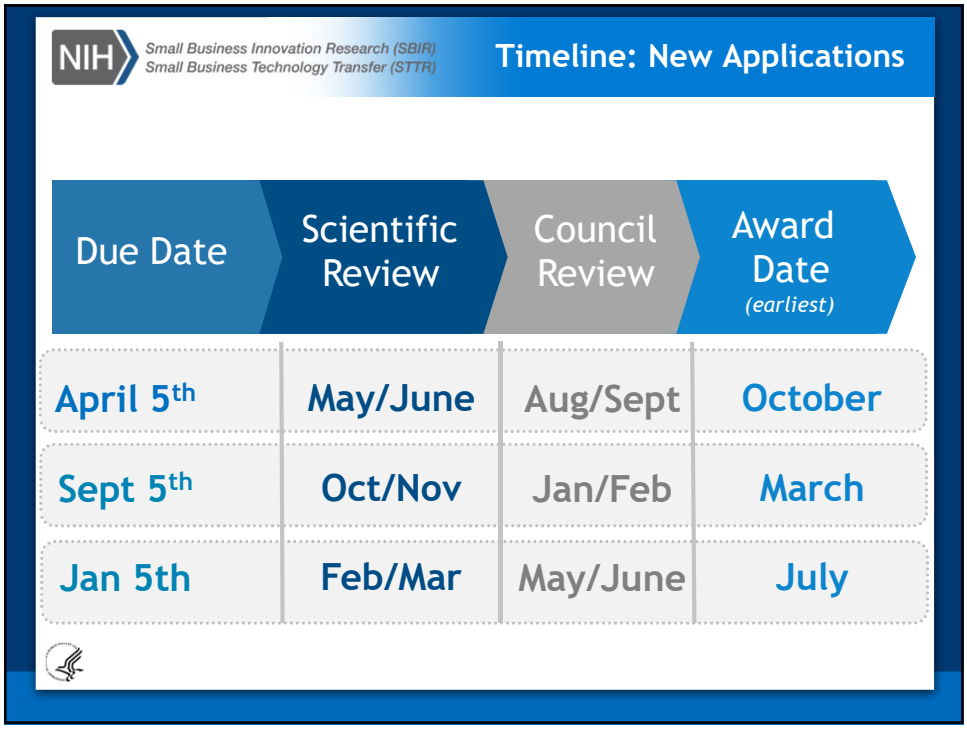
Application Assistance

SBIR/STTR Applicant Assistance Program

NIH AAP PROGRAM	NOT PROVIDED
Phase I Preparation Support and Review	Grant Writer
Specific Aims Page Review and Advice	Development of Research Plan
Submission Process Coaching	Register small business for you, apply to NIH for you

- AAP is FREE!
- For companies without previous NIH SBIR/STTR award
- Short, simple application

Sign up for our mailing list at https://sbir.cancer.gov to receive an alert for future cohorts!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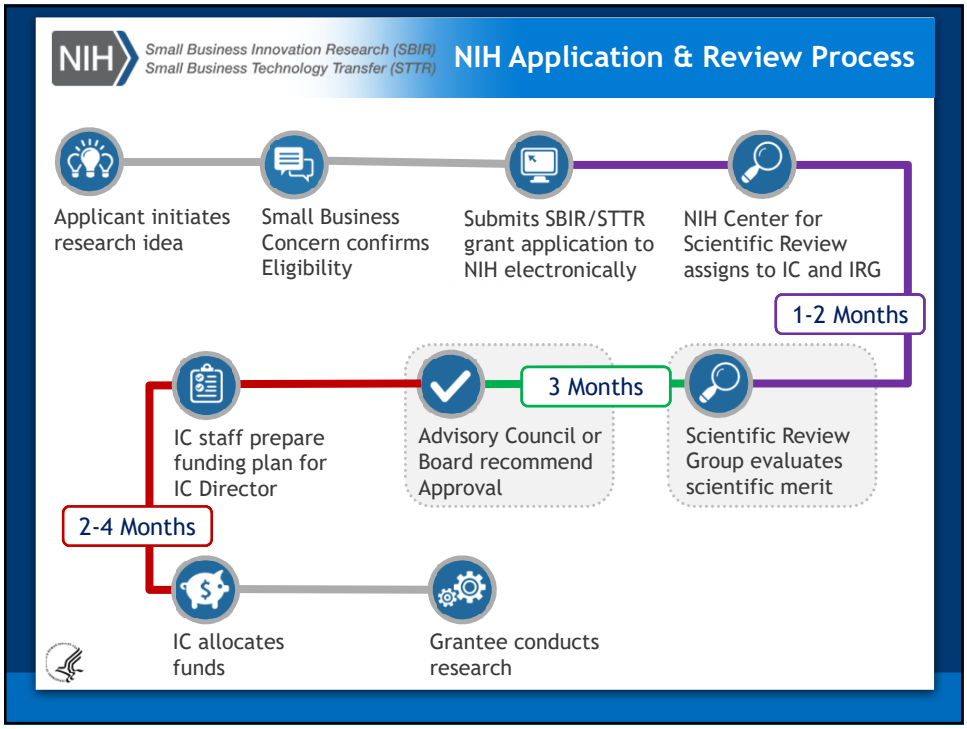
Timeline: New Applications
Due Date
Scientific Review
Council Review
Award Date
(earliest)
April 5th
May/June
Aug/Sept
October
Sept 5th
Oct/Nov
Jan/Feb
March
Jan 5th
Feb/Mar
May/June
July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NIH Application & Review Process
Applicant initiates research 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
Scientific Review Group evaluates scientific merit
3 Months
Advisory Council or Board recommend Approval
IC staff prepare funding plan for IC Director
2-4 Months
IC allocates funds
Grantee conducts research

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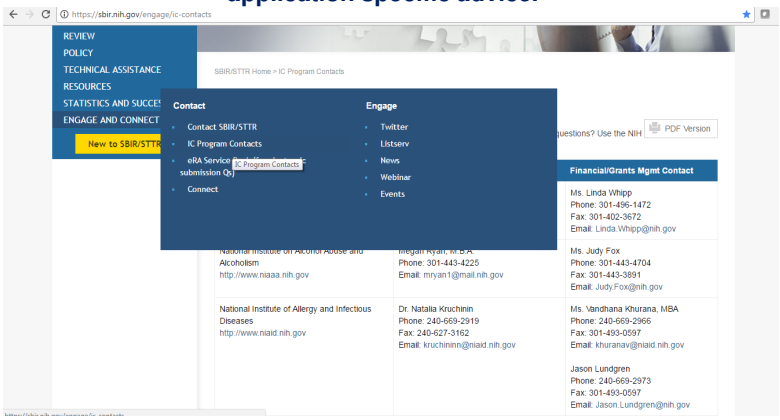
Most Important Piece of Advice

Talk to a HHS Program Officer at least a month 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

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WOSB and SDB Definitions

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

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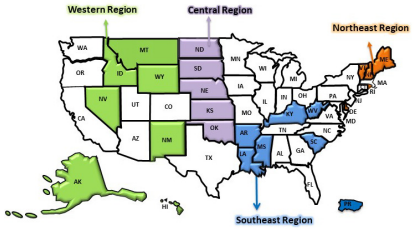
Encouraging Entrepreneurship: STTR Accelerator Hubs

- A new initiative in response to Congressional directive
- 4 IDeA Regions (Institutional Development Award (IDeA))
- One hub per region to provide infrastructure and encourage entrepreneurship within the regional culture.
- Training, mentoring, consulting services in:
  - Entrepreneurship
  - Technology transfer
  - IP protection and marketing
  - Small business finance
  - Business development
  - Partnerships



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Encouraging Entrepreneurship: STTR Accelerator Hubs

IDeA Region	Program Name	Small Business Concern	Major Academic Partnering Institution
Northeast	DRIVEN: Accelerating Medical Entrepreneurship in the Northeast	CELDARA MEDICAL, LLC, Lebanon, New Hampshire	University of Vermont, Burlington, Vermont
Central	The Sustainable Heartland Accelerator Regional Partnership (SHARP) Hub	BBC ENTREPRENUERIAL TRAINING AND CONSULTING, LLC, Chelsea, Michigan	University of Kansas Medical Center, Kansas City, Kansas
Western	ASCEND, Accelerating Solutions for Commercialization and Entrepreneurial Development in the Mountain West IDeA States	VIRTICI, LLC, Seattle, Washington	University of New Mexico Health Sciences Center, Albuquerque, New Mexico
Southeast	Southeast Xlerator Network	XLERATEHEALTH, LLC, Louisville, Kentucky	University of Kentucky, Lexington, Kentucky

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What technical assistance and resources programs are available for Small Business Concerns and academic entrepreneurs to assist in commercializing their NIH-funded technologies?

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NIH Technical Assistance Programs

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

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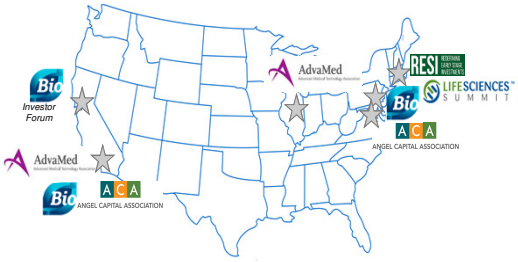
Multi-IC Technology Development Programs
(open to eligible Awardees from participating ICs)

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

12 Participating ICs + CDC

Facilitating Partnerships



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NCATS Additional Resources:
Bridging Interventional Development Gaps (BrIDGs)

- Model: Collaboration between Division of Preclinical Innovation (DPI) and extramural labs
- Projects
  - Enter with clinical candidate identified
  - Any disease eligible
  - Gap analysis followed by data generation using DPI resources and expertise to generate data necessary for IND filing
  - Exit at or before IND
  - Milestone driven
  - Therapeutic modalities: small molecules, peptides, oligonucleotides, gene therapy, antibodies, recombinant proteins
- Eligible Applicants
  - Academic (U.S. and Ex-U.S.), Non-Profit, SBIR-eligible businesses

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NCATS Additional Resources:
Therapeutics for Rare and Neglected Diseases (TRND) Program

- Model: Comprehensive drug development collaboration between DPI and extramural labs with disease-area/target expertise
- Projects
  - May enter at various stages of preclinical development
  - Disease must meet FDA orphan or WHO neglected tropical disease criteria
  - Taken to stage needed to attract external organization to adopt to complete clinical development/registration, max Phase 2a
  - Milestone driven
  - Therapeutic modalities: small molecules, proteins, peptides, oligonucleotides, gene therapy, antibodies, recombinant proteins
- Eligible Applicants
  - Academic, Nonprofit, Government Lab, Biotech/Pharma
  - Ex-U.S. applicants accepted

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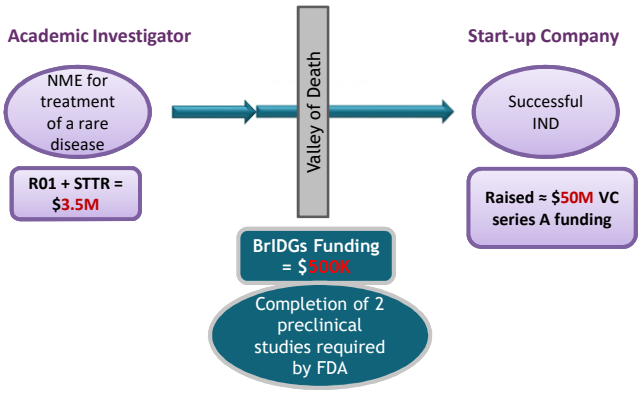
TRND/BrIDGs Project De-Risking Model
Minimum Time and Funding; Maximum Impact



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More Information

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Thank You For Your Attention

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Questions?