SBIR-STTR Program General Overview

Presented by
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USC Webinar Part 1

Capitalizing on Federal R&D

My Background

- 25+ years in the Federal Government
 - O NIH:
 - SBIR/STTR Program Manager: Office of the Director
 - Researcher: National Cancer Institute
 - O FDA
 - USDA
 - Interagency policies/initiatives (DOD, NSF, DOE, NASA, DHS, etc.)
- 10+ years in non-profit and for-profit environments
 - The Jackson Laboratory, Director of Sponsored Research
 - Small TX biotech company, VP Research
 - Small FL-based consulting company, Program Manager
- Scientific Background
 - Microbiology
 - Immunology
 - Cancer genetics



Topics to Discuss

- SBIR/STTR Overview
- Program eligibility
- Principal Investigator eligibility
- Relationship between a faculty member, university, and company

Dates for Upcoming Webinars!

- Sept 21: SBIR/STTR Application Structure and the NIH Peer Review Process
- Sept 28: How to Write your NIH SBIR/STTR Specific Aims Page and Commercialization Plan

SBIR/STTR Overview

SBIR/STTR History Review

SBIR - created by Federal legislation in 1982.

Roland Tibbets Ronald Reagan

- SBIR created to provide funding for <u>early-stage</u> innovative ideas that are <u>too high risk</u> for private investment.
- Envisioned as an "Economic Stimulus"
 - Strong signal to Federal Agencies to make more effective use of innovative scientists and engineers employed by small companies that have the potential to convert R&D funds into new products and create new jobs to optimize return on taxpayers' dollars.

Largest and most important source of early-stage technology R&D financing for America's Entrepreneurs!

\$>40B 450K scientists/engineers

SBIR/STTR Program Descriptions

Small Business Innovation Research (SBIR)

- Set-aside program for <u>small businesses</u> to engage in Federal R&D – with potential for commercialization
- 3.2% of the extramural research budget for agencies with a budget greater than \$100M per year
 - ~\$3.2 billion to spend each year

Small Business Technology Transfer (STTR)

- Sister set-aside program to facilitate <u>cooperative</u> R&D between <u>small businesses</u> and U.S. <u>research institutions</u> – with potential for commercialization.
- 0.45% of the extramural research budget for agencies with a budget greater than \$1B per year
 - ~\$450 million to spend each year

Over 5,000 new awards every year

SBIR/STTR Program Objectives

- Goal is to commercialize new innovations from U.S. small businesses:
 - 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
 - Foster technology transfer through cooperative R&D between small businesses and research institutions (STTR)
- Significant risk reduction:
 - Funds projects too early to attract investment capital

SBIR/STTR Program Structure

Feasibility -Proof of Concept

PHASE I (Feasibility Study)

- Award: Generally, up to \$250,000 TC*
- Project Period: Generally, 6 mos (SBIR); 1 yr (STTR)

Development Full R&D

PHASE II (Full Research/R&D)

- Award: Generally, up to \$750,000*
- Project Period: Generally, 2 years (SBIR/STTR)

PHASE IIB (Competing Renewal/R&D)

- Clinical R&D; Complex Instrumentation/Tools
- Award/Project Period: Generally, \$3M/3 years (NIH)

ommercial ization

PHASE III (Commercialization Stage)

Does not use of SBIR or STTR funds

*As of July 2023, agencies may issue a Phase I award up to **\$295,924** and a Phase II award up to **\$1,972,828** without seeking SBA approval. Any award above those levels requires a waiver.

Program Eligibility

SBIR Program Eligibility Criteria

- Applicant is organized as a for-profit business based in the U.S.
- 500 employees or less, including affiliates*
- PI's primary employment must be with the small business
- Eligibility is determined at the time of award
- * If company is a joint venture, additional requirements must be met:

https://www.sbir.gov/faqs/eligibility-requirements

STTR Program Eligibility Criteria

- Applicant is organized as a for-profit small business - based in the U.S.
- 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 intellectual property and rights to carry out Follow-on R&D and commercialization effort 11

Principal Investigator (PI) Eligibility

Principal Investigator (PI) Eligibility SBIR:

- Primary employment of PI <u>MUST</u> be with the Small Business
- More than 51% time must be spent with the Small Business
- Not required to Spend 51% on Project -- Just in Company
- No minimum time required to be spent on project (10% -20% is typical)
- **Note:** 51% does not mean working 20+ hours per week at Small Business while still employed F/T by University.

STTR:

 The PI may be from either the small business or the partnering institution

More on PI Rules

- For both SBIR and STTR awards, the Small Business PI and the University PI for the subcontract must be different individuals.
- If a University employee (or his/her spouse or dependent child) has a financial interest, leadership position in, or is employed by the Small Business, the faculty employee may not serve as the PI on the University subcontract from that Small Business.
- Establishing a separation of entities and roles is important.
 - Having the same person on both sides of the collaboration blurs the respective parties' project roles, responsibilities and effort/time commitments.
 - Some agencies may be more restrictive (e.g., NSF).

Still More on PI Rules

SBIR:

- Primary employment with Small Business precludes fulltime employment at another organization.
- Therefore, a full-time employee of the University may not serve as the PI of the SBIR grant.
- Options: PI takes a leave of absence from the University or assigns someone else as PI
- Multiple PI project: At least one must meet the primary employment requirement.
- Occasionally, funding agency allows deviations from the primary employment requirement - rare.

Even More Still on PI Rules

STTR:

- The PI may be employed with the Small Business or the participating non-profit research institution as long as s/he has a formal appointment with or commitment to the applicant small business
 - Characterized by an official relationship between the small business and that individual.
 - May or may not involve salary or other remuneration.
- The PD/PI must commit at least 10% effort to the project.
- Combined with University activities, effort may not exceed 100%.

Subcontractor Eligibility - SBIR

- Small Business may subcontract with a nonprofit research institute (and is encouraged!)
- Small Business should typically perform 2/3 of the work based on budget in Phase I. (50% of the work in Phase II)
 - Deviations must be justified and approved by NIH.
- Subcontracts may be with another company, university or other nonprofit organization.

Subcontractor Eligibility - STTR

- Small Business must partner with a nonprofit research institution
- Small Business must perform at least 40% of the effort (both Phases)
- Research Institution must perform at least 30% of the effort (both Phases)
- Balance of effort can go to either or additional parties (e.g., large company)
- IP agreement must be negotiated between parties

Research Space, Faculty, and COI

Use of University Space

- The Small Business must have space that it owns or controls to perform its R&D.
 - If use of University facilities by the Small Business is anticipated, use must be approved and covered by an agreement (Lease or License).
- Small Business certifies that their portion of R&D will occur in small business facilities using company employees unless otherwise indicated in the application and approved in the funding agreement.
- Performing the Small Business portion of R&D in University space using University resources – unless specifically approved by the funding agency and allowed by the University – subjects the company to potential criminal, civil, or administrative sanctions.

Things to Consider for Faculty

- Planning Phase: 1- 4 months
- RI PI should disclose invention to its appropriate research institution office
- RI PI should discuss collaboration with Small Business and identify a FOA
- If Human Subjects are involved in the research determine who will perform what activities?
 University? Company?
- Discuss potential Conflict of Interest (COI) issues with your institution

More on COI

- NIH exempts Phase I SBIR/STTR programs from federal COI regulations.
- Therefore, the University is not required to disclose to NIH any relationship or COI that the SBIR/STTR may create with a faculty member.
- However, University policy may be stricter and require that faculty disclose all financial relationships with the private sector in their annual COI disclosure, including information about participation in SBIR or STTR grants.

Even More on COI....

- Some University policies state that for funded Phase I SBIR and STTR programs, full disclosure is considered to be a sufficient management plan for the conflicts in most cases.
- During Phase II, however, Pls must comply with federal regulations for disclosure and manage any apparent/actual COI.

Scenario A: University employee (or family member) with NO significant financial interest

- Typically, the University employee may participate in or serve as a PI of a <u>subcontract</u> on SBIR/STTR projects if s/he has no ownership interests, is not employed by or has a position with the Small Business or has no other significant financial interests.
- In some cases (determined by COI office), the University employee may serve as a PI of a STTR project.

Scenario B: Ownership Interest, Employment, or Financial Interest Related to IP

- University employee cannot be PI for the Small Business and PI of a subcontract on the same SBIR or STTR project.
- University employee cannot work at both the company and the University on research related to SBIR or STTR projects.
- University employee who has an ownership interest in a Small Business cannot conduct or supervise research activities in his/her University laboratory through subcontracts on SBIR or STTR projects awarded to the Small Business.
- University employee paid directly from a Small Business with whom they have an ownership interest cannot conduct research for that entity in their University laboratory space.

SBIR/STTR Participating Agencies

SBIR and STTR Participating Agencies

Department of Agriculture (USDA)

Department of Commerce (DoC)
NIST, NOAA

Department of Defense (DoD)

Department of Education (ED)

Department of Energy (DOE)

Dept of Health and Human Services (HHS) NIH, FDA, CDC, ACL

Department of Homeland Security (DHS)

Department of Transportation (DOT)

Environmental Protection Agency (EPA)

National Aeronautics and Space Administration (NASA)

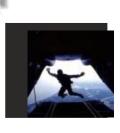
National Science Foundation (NSF)

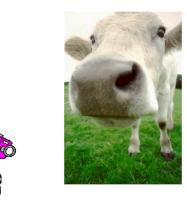
Federal R&D Agencies Are All Different...Mission And Culture































Program Differences Between Agencies

Solicitations

- Number of Solicitations single vs. multiple annually
- Topic Areas broad vs. focused

Proposals

- Proposal Preparation Instructions no unified process
- Proposal Review Process external peer review or internal review
- Proposal Success Rates vary between agencies

Awards

- Type of Award Contract, Grant, Cooperative Agreement
- Financial Details indirect cost rates
- Dollar Amount of Award
- Gap funding

Federal Agency Differences

Federal Agency Comparison												
	DOD	NIH	DOE	NASA	NSF	USDA	DOC	DHS	VA	DOT	EPA	ED
Award Type Contract (C) Grant (G)	C/G	G/C	G	С	G	G	С	С	G/C	С	С	G/C
Review Process Internal (I) External (E)	I	E	E	ı	E	E	I	I	I	I	I	I
Research Topics Specific (S) Broad (B)	s	В	s	s	В	В	s	s	S	s	s	s
Communication Restricted (R) Open (O)	R	0	R	R	0	o	R	R	R	R	R	0
Investigator-Initiated Ideas	N	Y	N	N	Y	Y	N	N	N	N	N	N
Gap Funding	Y	Y	Y	N	Y	Y	N	N	N	N	N	Z

Standard SBIR/STTR Phase I Process

Solicitation **Topics** 4-9 Months Proposal Submission **Evaluation** Ph I Award Grant/Contract)

- Agencies describe R&D topics in solicitations at fixed time periods over the year – generally not rolling.
- Small Business prepares/submits proposal.
- Agencies evaluate based on technical merit, company's qualifications, and commercial potential / societal benefit.
- Agencies make Phase I awards.

Differences Between SBIR and STTR Programs

	SBIR	STTR					
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner					
Principal Investigator	Primary employment (>50%) must be with the small business	Requires a non-profit research institution partner PI may be employed he research institution partner small by is Alayadee and amandames arch Institution Partner 0.45% set-aside					
Work Requirement	May subcontract up to: 33% (Phase I) 50% (Phase II)	usiness and amainess arch Institution Partner					
Program Size	3.2% set-asi The appli	0.45% set-aside					
Majority VC ownership	Allowed by son. Jgencies	Not allowed					
Participating Agencies	11 agencies (extramural R&D budget > \$100M)	5 agencies (extramural R&D budget > \$1B)					

Required Registrations

- Dun and Bradstreet DUNS #
- System for Award Management (SAM)
- SBA Company Registration
- NSF: Fast Lane Company and PI Registration
- NIH: eRA Commons Signing Official and PD/PI
- DOD: Defense SBIR/STTR Innovation Portal

National Institutes of Health











Mission:

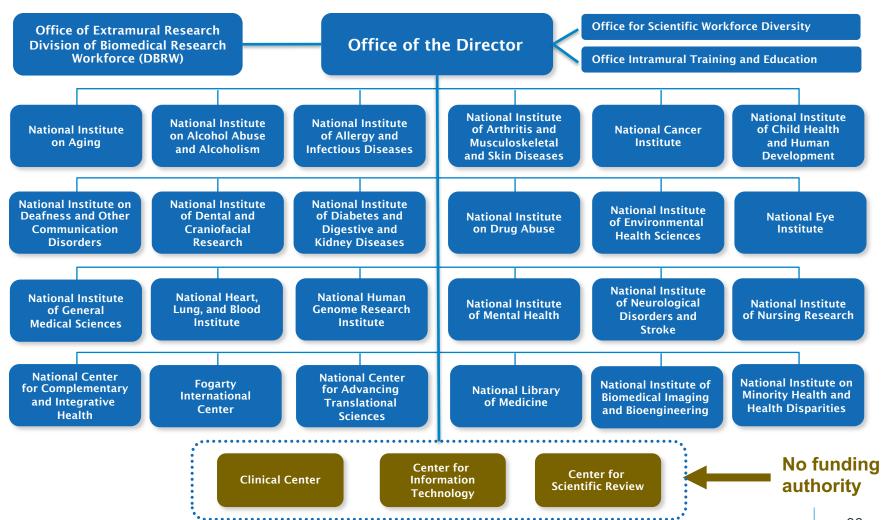
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.





National Institutes of Health

The largest public funder of biomedical research in the world, investing more than \$50 billion in FY22 to enhance life, and reduce illness and disability.



ONE NIH, 27 Cultures

Each Institute/Center has its own

- mission
- budget (and success rates)
- activities
- way of doing business

You are in the right place to learn the myriad nuances!

NIH SBIR/STTR Budget Allocations FY2023 3.2% SBIR \$1.1 billion 0.45% STTR \$146 million **NIMHD** Total FY23 \$1.2 billion **NCCIH** NIDCD NIBIB **ORIP** NIAAA NLM NIAMS NHGRI NIDCR **Environmental Health Translational Sciences Cancer** Eye **Child Health** Allergy and **Drug Abuse Infectious Diseases Mental Health** Diabetes, Digestive, and **Kidney Disorders Aging Neurological Disorders and Stroke** Heart, Lung, and **General Medical Blood Sciences** 38

National Institutes of Health

- Posts broad topics <u>and</u> targeted initiatives
 - Omnibus Solicitations
 - RFAs, PAs
 - Encourages "investigator-initiated" research ideas
- Open communication
 - Contact with Program Director is encouraged throughout the process
 - Share draft Specific Aims and discuss
 - Discuss Budget, Team, etc.
 - Understand IC priorities
 - PHS Assignment Request Form: Use to impact study section makeup and IC assignment
- Reviewer roster is shared with applicant
- Reporting: Not onerous (relatively speaking)

NIH SBIR/STTR Phases

Discovery Development

Phase I Phase II





Feasibility Full R & D

Phase I --> Phase II

Fast-Track

Direct to Phase II (SBIR only) Commercial Market
Phase III

Competing Renewal
Award
Phase IIB



Up to \$300K (see FOA)

Only Some NIH
Institutes/Centers participate

Phase I: \$295,924* 1-2 years

Phase II: \$1,972,828*

1-3 years

*NIH has a waiver from the Small Business Administration to exceed these budgets for most topics

NIH Small Business Program Phases

Small Business Program Phases	Description				
Phase I	A Phase I award helps you focus on the feasibility, technical merit, and commercial potential of your research project.				
Phase II	A Phase II award lets you continue the research and development efforts initiated in Phase I. Once you've reached your Phase I milestones, you can apply for a Phase II award, even before the end of the Phase II award. You may submit your application for a Phase II award up to six receipt dates after your Phase I budget period expires.				
Fast-Track	The fast-track process allows you to submit both Phase I and Phase II in one application for review. The Fast -Track mechanism can minimize the funding gap between phases but requires a fully developed Phase II application/plan at the time of submission.				
Direct to Phase II (SBIR Only)	If your project has already demonstrated feasibility but you have not received a Phase I SBIR or STTR, you can apply for a Direct to Phase II award and bypass Phase I.				
Phase IIB More info here	Some NIH Institutes and Centers offer Phase IIB awards for Phase II projects that require extraordinary time and effort beyond the standard Phase II period of 2 years. See the <u>Phase IIB FAQs</u> for more information.				
Commercialization Readiness Pilot (CRP) Program <u>FOA</u>	The Commercialization Readiness Pilot (CRP) Program provides awarded Phase II and Phase IIB small businesses technical assistance and funding for late-stage development. Read more about the CRP program . More info here				

Technical Assistance and Entrepreneurial Training

Discovery
Phase I



Development
Phase II/IIB



Technical and
Business
Assistance
(TABA) Programs

TABA Funding: Requested in the Application
Phase I- \$6,500/year Phase II- \$50K

Needs Assessment Click here for details

Consulting Services Click here for details

Additional
Entrepreneurial
Training and
Assistance

NIH I-Corps™ Click here for details

NIH Concept to Clinic Commercializing Innovation (C3i): Medical Devices

Click here for details

Diversity Supplement (PA-21-345)

https://sbir.nih.gov/tap

NIH Key Priority Areas

- NIH Strategic Plan 2021-2025
- Advancing Biomedical and Behavioral Sciences
 - Driving foundational science
 - Inventing tools and technologies to catalyze discovery
 - Preventing disease and promoting health
 - Developing new/improved vaccines
 - Developing and Optimizing Treatments, Interventions and Cures
 - Catalyzing Cell Engineering, Bioengineering, Regenerative Medicine
- Developing, Maintaining and Renewing Scientific Research Capacity
 - Enhancing biomedical Workforce
 - Some SBIR FOAs focus on workforce development
- Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability and Social Responsibility in the Conduct of Science
 - Promoting good stewardship
 - Leveraging partnerships (Federal, PPP, etc.)

NIH Funding Opportunities Abound!

- Omnibus Solicitations SBIR
- SBIR Program: PA-23-230 (Clinical trial not allowed)
 - PHS 2023-2 Omnibus Solicitation of the NIH, CDC and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial Not Allowed)
 - Receipt Dates: September 5, 2023; January 5, 2024; April 5, 2024
- SBIR Program: PA-23-231 (Clinical trial required)
 - PHS 2023-2 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial Required)
 - Receipt Dates: September 5, 2023; January 5, 2024; April 5, 2024

Focus is on Investigator-initiated research

NIH Funding Opportunities (cont.)

- Omnibus Solicitation STTR
- STTR Program: PA-23-232 (Clinical trial not allowed)
 - PHS 2023-2 Omnibus Solicitation of the NIH for Small Business
 Technology Transfer Grant Applications (Parent STTR [R41/R42]
 Clinical Trial Not Allowed)
 - Receipt Dates: September 5, 2023; January 5, 2024; April 5, 2024
- STTR Program: PA-23-233 (Clinical trial required)
 - PHS 2023-2 Omnibus Solicitation of the NIH for Small Business
 Technology Transfer Grant Applications (Parent STTR [R41/R42]
 Clinical Trial Required)
 - Receipt Dates: September 5, 2023; January 5, 2024; April 5, 2024

NIH Funding Opportunities (cont.)

Examples of Targeted Opportunities (NIH Guide)

Notice of Special Interest (NOSI): Advancing Biomedical Research in Pulmonary Non-Tuberculous Mycobacterial (NTM) Infections	NOT-AI-23- 050	NIAID	Jun 27, 2023	Jul 17, 2026
Notice of Special Interest (NOSI): Using Targeted Degradation of Protein and non- Protein Targets for the Development of Novel Anti-Infectives	NOT-AI-23- 049	NIAID	Jun 23, 2023	Jul 17, 2026
Limited Competition: Human Pangenome Coordinating Center (U41) Clinical Trial Not Allowed	RFA-HG-23- 025	NHGRI	Jun 20, 2023	Aug 16, 2023
Notice of Special Interest (NOSI): Promoting Research and Development of Vaccines Against Enteric Viruses	NOT-AI-23- 048	NIAID	Jun 15, 2023	Jul 17, 2026
Interactive Digital Media (IDM) Biomedical Science Resources for Pre-College Students and Teachers (SBIR) (R43/R44 Clinical Trial Not Allowed)	PAR-23-213	NIGMS	Jun 15, 2023	Sep 06, 2025
Field-Deployable, Low-Cost Point-of-Need Approaches and Technologies to Lower the Barriers to Substance Use Disorders (SUD) Diagnosis and Treatment (R43/R44 Clinical Trial Optional)	RFA-DA-24- 018	NIDA	May 23, 2023	Nov 11, 2023
Field-Deployable, Low-Cost Point-of-Need Approaches and Technologies to Lower the Barriers to Substance Use Disorders (SUD) Diagnosis and Treatment (R41/R42 Clinical Trial Optional)	RFA-DA-24- 017	NIDA	May 23, 2023	Nov 10, 2023
Notice of Special Interest (NOSI): Developmentally Tailored HIV Prevention and Care Research for Adolescents and Young Adults	NOT-MH-23- 250	NIMH	May 19, 2023	Sep 08, 2026

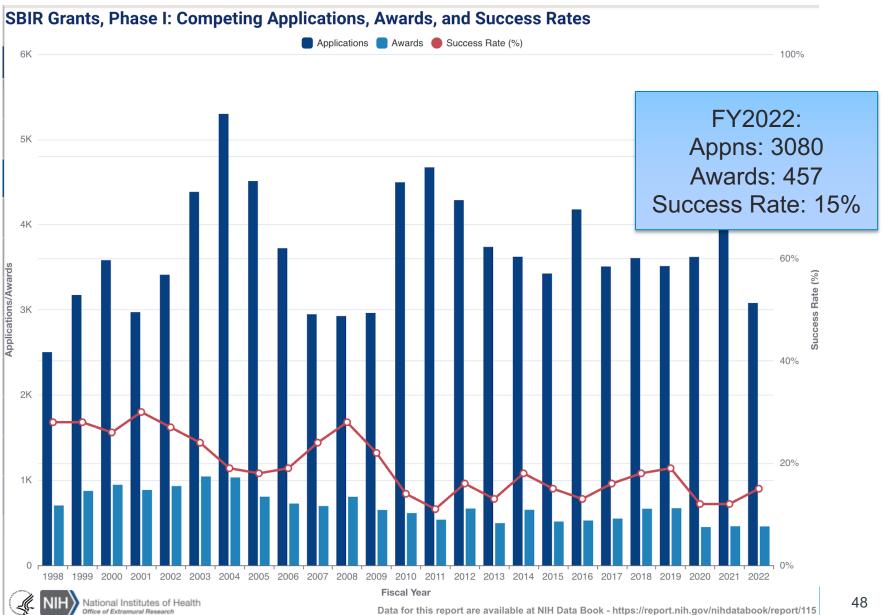
National Institutes of Health

Examples of Targeted Opportunities (cont.)

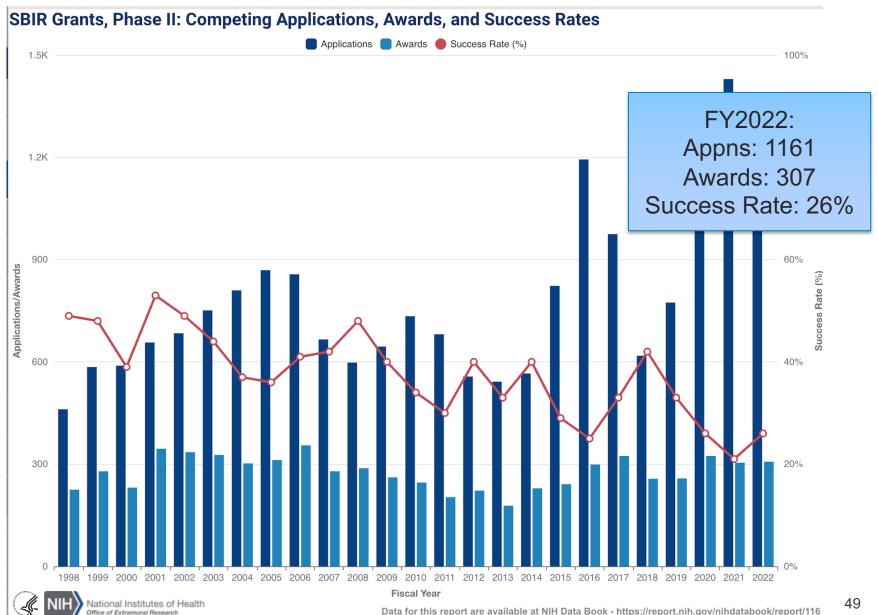
Small Business Transition Grant For Early Career Scientists (R42 Clinical Trial Not Allowed)	RFA-CA-23- 035	NCI	Apr 21, 2023	Aug 22, 2023
SBIR Phase IIB Bridge Awards to Accelerate the Development of Cancer-Relevant Technologies Toward Commercialization (R44 Clinical Trial Optional)	RFA-CA-23- 034	NCI	Apr 21, 2023	Aug 22, 2023
Industrialization and Translation of Extracellular Vesicles for use in Regenerative Medicine (U43/U44 Clinical Trials Not Allowed)	PAR-23-267	NCATS	Apr 18, 2023	Jun 07, 2025
Developing Regulated Therapeutic and Diagnostic Solutions for Patients Affected by Opioid and/or Stimulants use Disorders (OUD/StUD) (R41/R42 Clinical Trial Optional)	RFA-DA-24- 038	NIDA	Apr 18, 2023	Feb 15, 2025
Notice of Special Interest (NOSI): Synthetic Biology for Biomedical Applications.	NOT-EB-23- 002	NIBIB	Apr 14, 2023	May 17, 2026
Notice of Special Interest (NOSI): Development of Innovative Informatics and Data Science Technologies, Tools, and Methods for Vision Research	NOT-EY-23- 005	NEI	Apr 3, 2023	Feb 16, 2026
Notice of Special Interest (NOSI): Promoting Language and Communication in Minimally Verbal/Non-Speaking Individuals with Autism	NOT-DC-23- 009	NIDCD	Apr 3, 2023	Jun 06, 2026
NHLBI Notice of Clarification and Availability of Frequently Asked Questions (FAQs) for RFA-HL-23-008 and RFA-HL-23- 009 "NHLBI SBIR Phase IIB Small Market Awards"	NOT-HL-23- 082	NHLBI	Mar 16, 2023	N/A

MORE: https://seed.nih.gov/small-business-funding/find-funding/sbir-sttr-funding-opportunities?sorton=reldate&sort Direction=DESC&table=nonparent #nonparenttable

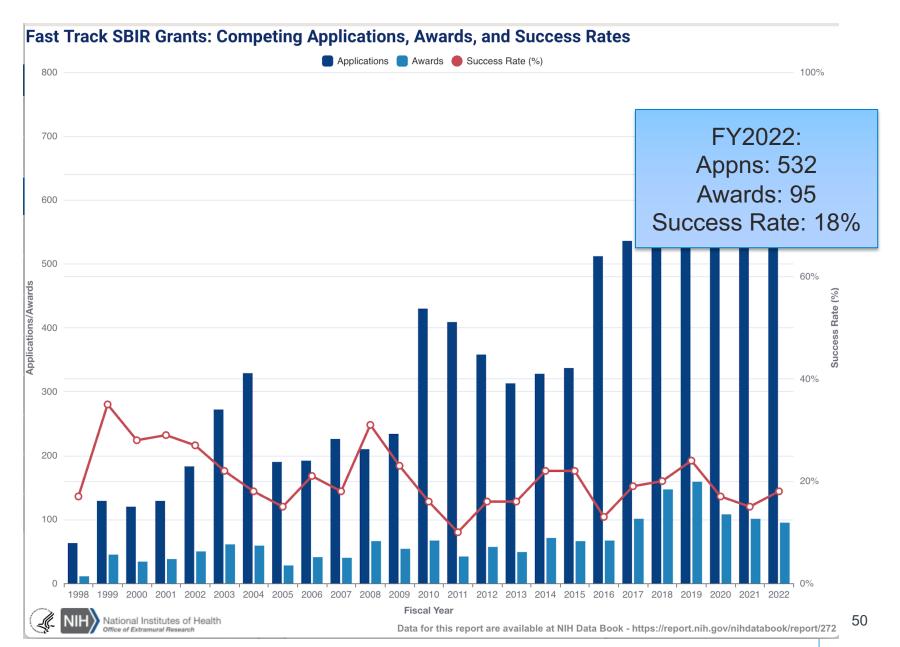
NIH Phase I Success Rate Data



NIH Phase II Success Rate Data



NIH Fast-Track Success Rate Data



Common Application Problems

Problems with Significance

- Scientific premise is weak or not even stated
- Neither significant nor exciting new research (i.e., won't advance science)
- Lack of compelling rationale
- Incremental science; low impact research

Problems with Innovation

- Not clearly addressed in application
- Not a new technology or improvement over existing technology

Problems with Specific Aims

- Dependent upon one another
- Too ambitious, too much work proposed
- Unfocused aims, unclear goals
- Limited aims and uncertain future directions

Common Application Problems (cont.)

Problems with Experimental Approach

- Insufficient detail on approaches
- Too much unnecessary experimental detail
- Insufficient preliminary data (or literature research) to show likelihood of establishing feasibility
- Lack of specific, quantifiable, and testable feasibility milestones
- Little or no expertise with approach
- Lack of appropriate controls
- Lack of biostatistician
- Missing potential pitfalls/alternative strategies
- Ph II: Failure to demonstrate Ph I feasibility
- Ph II/FT: Weak Commercialization Plan

Common Application Problems (cont.)

Problems with Investigator/Team

- No demonstration of expertise or lack of publications regarding approaches
- Low productivity, few recent papers
- No collaborators recruited or no letters from collaborators
- Team has not worked together in the past

Problems with Environment:

- Facilities/Other resources not well described
- Necessary equipment is not available

Trans-Agency Research Topics (1)

- Advanced Communications Technologies
 - DOD; NIH; NASA; NSF; DOE; DOC
 - SBIR.gov Award Data
- Artificial Intelligence
 - All Agencies except ED
 - SBIR.gov Award Data
- Biotechnology
 - DOD; NIH; NSF; EPA; USDA
 - SBIR.gov Award Data
- High-Performance Computing
 - DOD; NIH; NASA; NSF; DOC
 - SBIR.gov Award Data

- Microelectronics
 - DOD; NIH; NSF; NASA; DOE;USDA; DOC
 - SBIR.gov Award Data
- Quantum Information Science
 - DOD; DOE; NSF
 - SBIR.gov Award Data
- Robotics
 - All Agencies except ED
 - SBIR.gov Award Data
- Space Technologies
 - DOD; NASA; NSF; DOE; DOC
 - SBIR.gov Award Data

Trans-Agency Research Topics (2)

- Advanced Materials
 - DOD; NIH; NSF; NASA; DOE; DOT
 - SBIR.gov Award Data
- Medical Devices
 - DOD; NIH; NSF; DOE
 - SBIR.gov Award Data
- Infectious Diseases
 - DOD, NIH; NSF; USDA; DOC; DHS
 - SBIR.gov Award Data
- Sensor Technologies
 - O DOD; NIH; NASA; NSF; DOE; EPA; NIST; NOAA; USDA; EPA
 - SBIR.gov Award Data

Award Examples – NIH-DOD SBIR

A New Filter Paper Technology for Flavivirus Collection, Shipping, and Analysis

Project Number 1R44AI132032-01

Contact PI/Project Leader NASARABADI, SHANAVAZ

Awardee Organization GENTEGRA, LLC

It is proposed that this SBIR-funded technology, which is based on a new class of inexpensive, chemically treated filter paper that has been invented with DARPA support, will revolutionize the use of sophisticated RNA testing in epidemiology and public health screening, where the samples of interest must be collected in low resource environment.

Antimicrobial Biodegradable Bone Graft for Craniofacial/Maxillofacial Application

Project Number 6R43DE023287-02

Contact PI/Project Leader ASLANI, ARASH

Awardee Organization N2 BIOMEDICAL, LLC

Military and civilian surgeons have a significant need for a biodegradable implant that can deliver antibiotics to the site of a bone fracture and replace craniofacial bone defects. Hospitalizations due to injuries and injury-related bone replacement and reconstruction were the leading cause of hospitalization for the Army, Navy and Marine Corps, and the second leading cause of hospitalization for the Air Force.

Development of a syringe/sonication device employed to administer DDFPe in the prehospital setting

Project Number 1R43NS105295-01 Contact PI/Project Leader UNGER, EVAN CHARLES

Awardee Organization NUVOX PHARMA, LLC

A therapy that can be deployed rapidly, and safely en route to the hospital for civilians and also for soldiers on the battlefield could greatly reduce the trauma mortality rates due to both hemorrhage and traumatic brain injury. Sonication of pre-filled syringes of dodecafluoropentane emulsion (DDFPe), an oxygen therapeutic, can be employed to produce in spec nanoemulsion suitable for IV administration.

SBIR/STTR Advantages

- Provides very early stage high-risk (high payoff) R&D product development funding
- Validation of your R&D efforts
- Provides leverage for follow on funding
- Non-dilutable source of capital
- Attractive to Investors
- Not a loan no repayment required
- No loss of equity ownership
- No royalty payback
- Intellectual property rights remain with the small business
- Preferences, including <u>sole source contracts</u>, for followon Phase III government funding or procurement possible

SBIR/STTR Disadvantages

- Many processes, policies, rules to follow
- Slow process (3-5 years through Phase II)
- Requires R&D capability and writing skills
- Must propose mission relevant projects
 - Very specific for contracting agencies
 - Much more leeway for granting agencies
- Government contracts and accounting can be onerous

Take Aways

- Understand the various agency cultures and your reviewer audience
- Be strategic about the grants you pursue
- Identify programs and potential partners/SMEs for initiatives that align with your project.
- Be proactive and meet with agency staff so you are well-positioned to apply
 - Develop value proposition Aims / White papers
- Be persistent!

Thank You!

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