



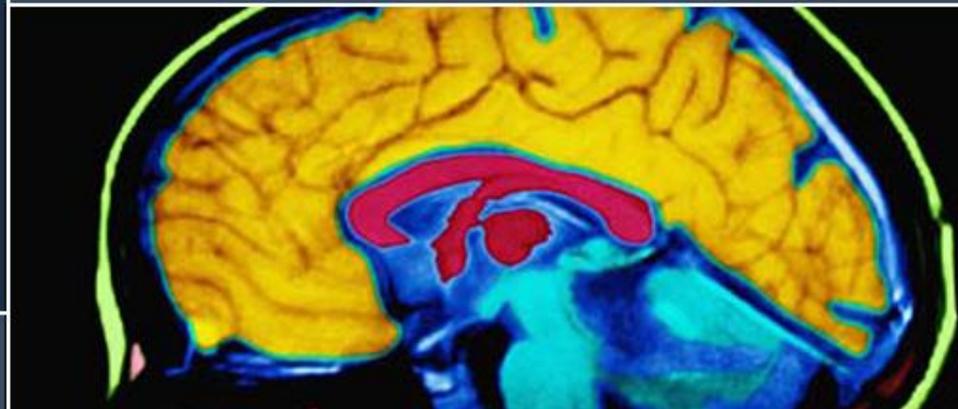
National Institute of
Neurological Disorders
and Stroke

Small Business Programs at NINDS

February 20, 2018



Stephanie Fertig, MBA
Director, NINDS Small Business Programs
Division of Translational Research, NINDS
fertigs@ninds.nih.gov



Select slides contain a “comment box” which has incorporated questions posed during the webinar. Look for this symbol:



on the slides.

The National Institute of Neurological Disorders and Stroke (NINDS)

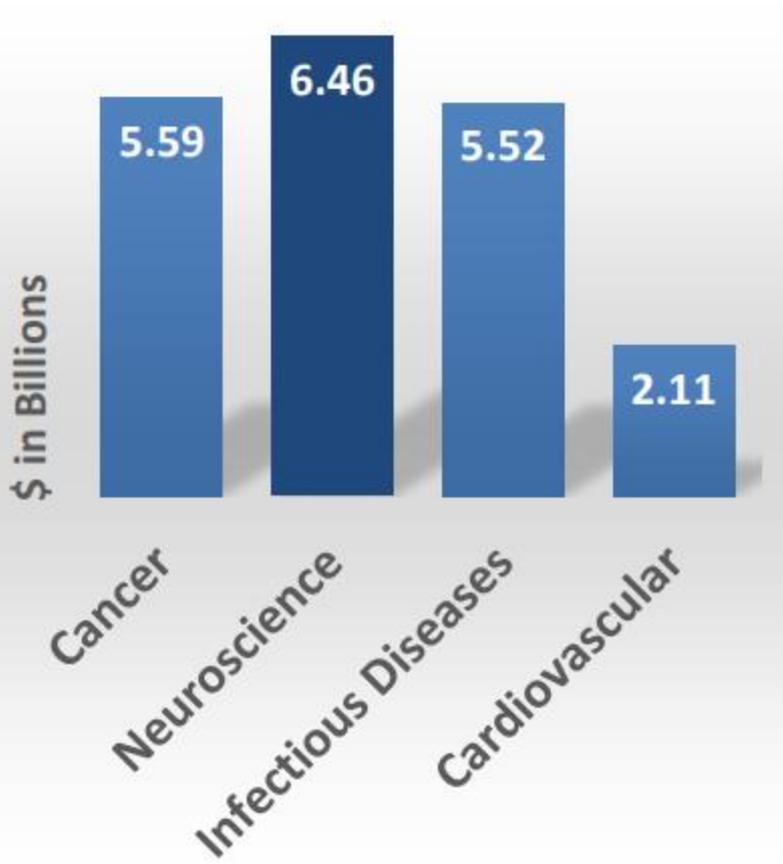


*The mission of NINDS is to seek
fundamental knowledge
about the brain and nervous system
and to use that knowledge to reduce
the burden of neurological disease*

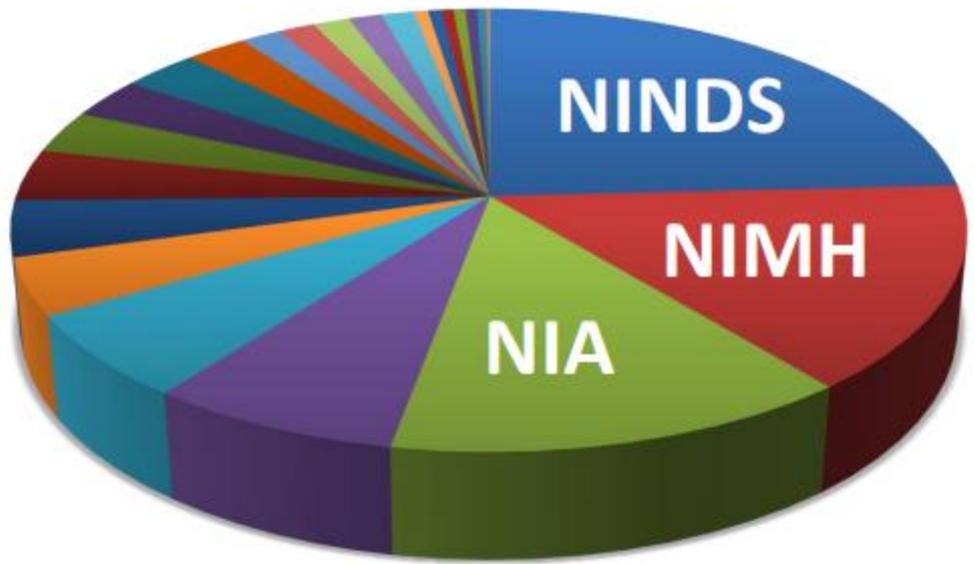
**Support research on hundreds of
Neurological Disorders**

<https://www.ninds.nih.gov/>

2016 NIH Neuroscience Funding



- | | | | |
|-------|-------|-------|-------|
| NINDS | NIMH | NIA | NEI |
| NIDA | NIDCD | NICHD | NCI |
| NIAAA | NIGMS | NHLBI | NIDDK |
| NIAID | OD | RMAP | NIEHS |
| NIBIB | NCCIH | NIAMS | NIDCR |



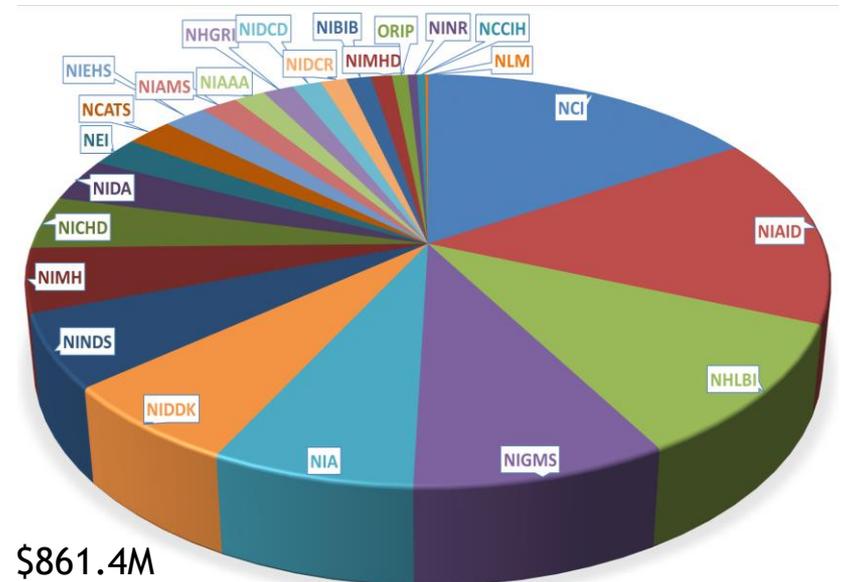
SBIR/STTR Tip

Each Institute/Center (IC) has different policies

- Applications come to the NIH (not to a specific IC)
- Important to know which IC will take assignment
 - Each IC has a different mission/focus
 - Different policies, budget guidelines, and resources

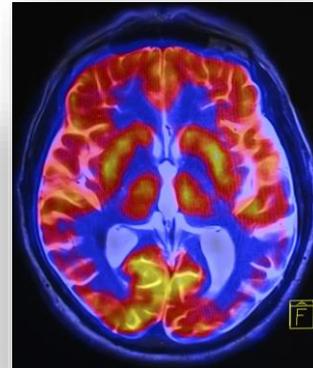
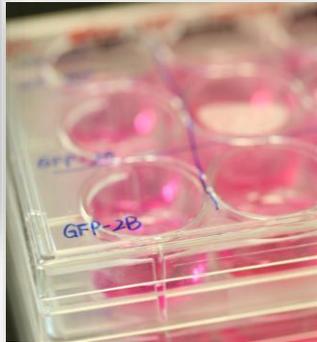
- **Contact NIH Program Staff well in advance of applying**

- We can help!
- Contact Me:
fertigs@ninds.nih.gov
- Contacts for each IC:
<https://sbir.nih.gov/engage/ic-contacts>



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

NINDS Is Investing Across the Research Spectrum



Basic

*Fundamental Neuroscience
Disease-Focused Research*

Translational

*Assay Development
Pre-Clinical Research*

Clinical

*Phase I, II, III Trials
FDA Review*

NINDS Translational and Clinical Programs

Preclinical and Early Clinical Trials

Grants

CounterACT: National Institutes of Health Countermeasures Against Chemical Threats

Translational Neural Devices

iGNITE: Innovation Grants to Nurture Initial Translational Efforts

CREATE BIO: Cooperative Research to Enable and Advance Translational Enterprises for Biologics

SBIR · STTR: America's Seed Fund

NEUROSCINECE BIOMARKER PROGRAM

NIH Blueprint for Neuroscience Research

Resources

Epilepsy Therapy Screening Program (ETSP)

Training

Contracts

ADME/Tox. Chemistry Manufacturing Clinical

PK/PD & ADME

GOOD MANUFACTURING PRACTICE GMP CONSISTENT QUALITY

CLINICAL TRIAL

Clinical Trials/ Infrastructure Resources

Grants

Dissemination and Implementation Research in Health (R01)

SBIR · STTR: America's Seed Fund

NINDS Exploratory Clinical Trials Program Announcements

NIH SIREN

NeuroNEXT

StrokeNet: PREVENTION | TREATMENT | RECOVERY. Funded by a Grant from the National Institutes of Health

NIH Programs

BRAIN Initiative: NIH Invests \$85 million for BRAIN Initiative research

Stimulating Peripheral Activity to Relieve Conditions (SPARC)

<https://www.ninds.nih.gov/>



SBIR · STTR
America's Seed Fund

NIH Small Business Programs

\$980M (NIH)

\$55M (NINDS)

Available for Small Businesses

- Congressionally mandated 3.65% set-aside
- For research with potential for commercialization
- Broad scope
 - Therapeutics, diagnostics, and tools for research
 - May include bench research, translational research, and early stage clinical trials
- Larger budgets for some topics (e.g. animal and clinical studies)
- A majority of our applications are investigator-initiated and come in through the omnibus solicitations

<https://www.ninds.nih.gov/Funding/Small-Business-Grants>

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 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)

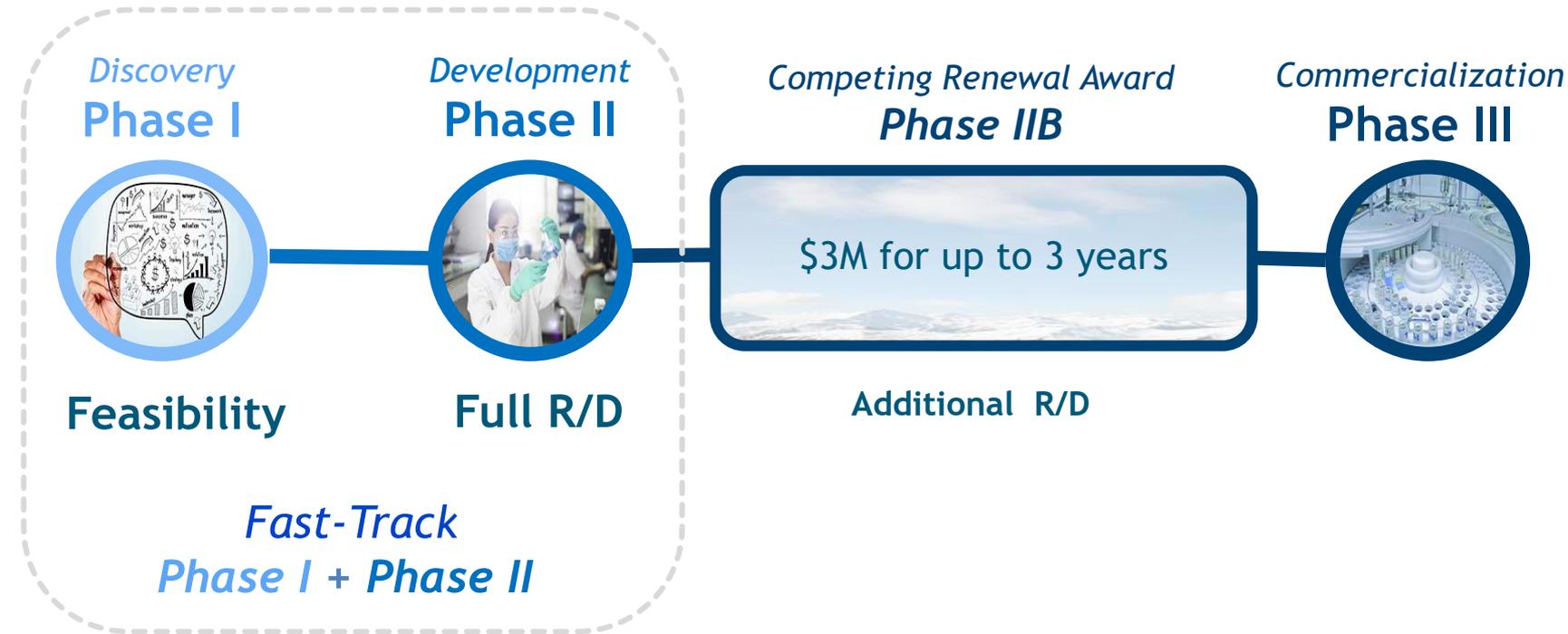
Determined at Time of Award

SBIR and STTR Critical Differences

	SBIR (Small Business Innovation Research)	STTR (Small Business Technology Transfer)
Required Set-Aside	3.2%	0.45%
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

Phases of SBIR/STTR



Phase I:
Guidelines: \$150K/6 months
Hard Cap*: \$225K/1-2 years
NINDS Waiver Guidelines: \$700K
(not more than \$500K/yr)

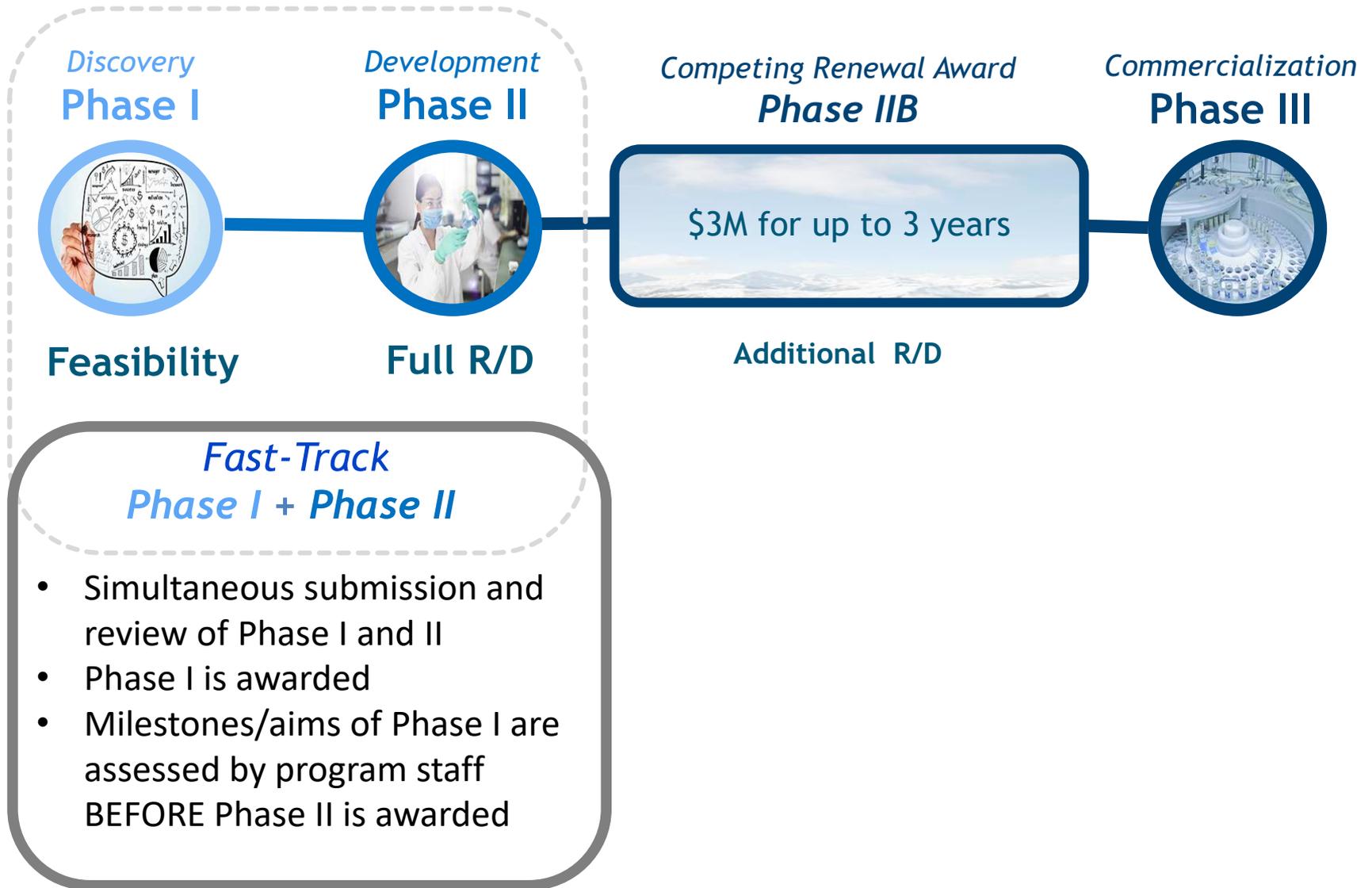


Phase II:
Guidelines: \$1M/1 year
Hard Cap*: \$1.5M/1-3 years
NINDS Waiver Guidelines: \$3M
(not more than \$1.5M/yr)

***NIH has a wavier from the Small Business Administration to exceed these Hard Caps for specific topics**

SBIR/STTR budgets are in total cost (direct + indirect + fee)

Fast-Track SBIR/STTR

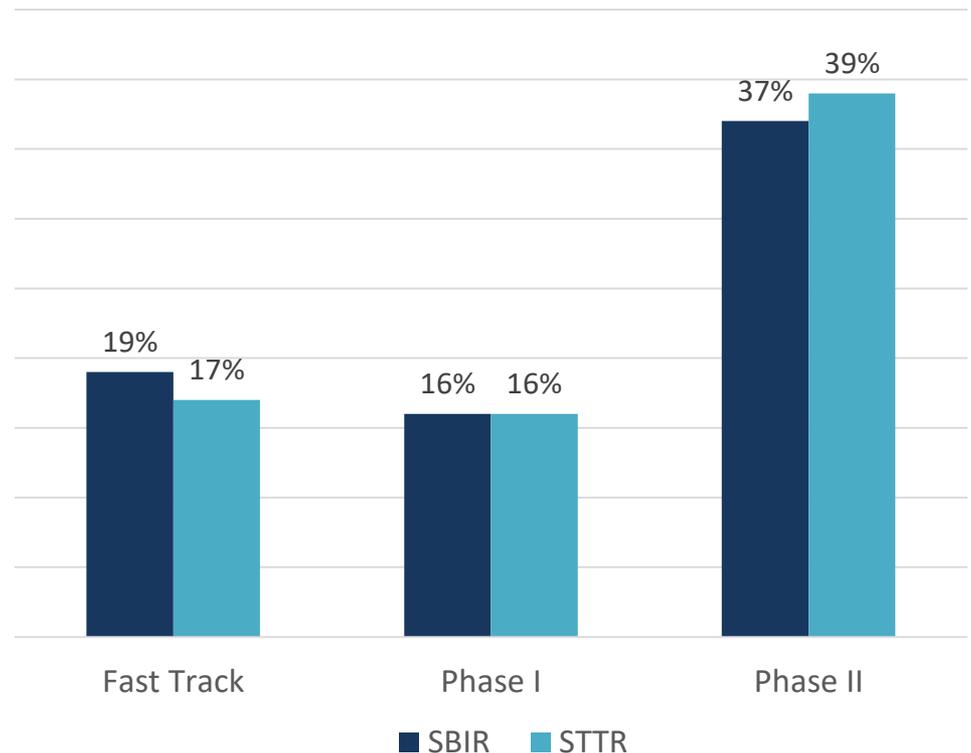


SBIR/STTR Tip

Pick the program that fits your project

- Consider the same score range for SBIR and STTR
- SBIR program has more than 7x the budget but has roughly the same application success rate at NIH
- Bonus Tip: Across NIH all new application types (Phase I and Fast-Track) have roughly the same success rate

Contact Us! We can help you determine what might be the best program for you



NIH Provides a Wealth of Information Online: NIH Small Business Programs Website

U.S. Department of Health & Human Services | National Institutes of Health

OER HOME | ABOUT GRANTS | FUNDING | FORMS & DEADLINES | GRANTS POLICY | ERA | NEWS & EVENTS | ABOUT OER

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

SBIR • STTR
America's Seed Fund

SBIR/STTR HOME
ABOUT
FUNDING
APPLY
REVIEW
POLICY
TECHNICAL ASSISTANCE
RESOURCES
STATISTICS AND SUCCESS STORIES
ENGAGE AND CONNECT

New to SBIR/STTR

Resources

- Application Instructions
- Annotated Form Set
- Sample SBIR Applications from NIAID
- NIH SBIR/STTR Just-in-Time (JIT) Procedures
- Agency and State Contacts
- Life Science Contacts by State
- NIH SBIR/STTR Fact Sheet
- Events
- Webinars
- Financial Questionnaire
- FAQs

Electronic Submission Process

The electronic application submission process for HHS SBIR and STTR grants is multi-step, and can take six to eight weeks to complete the five registrations required for electronic submission.

Technical Assistance Programs | Funding | Clinical Trials | **Electronic Submission Process** | Success Stories | Contact Us

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.

HHS SBIR/STTR COMPONENT PROGRAM LINKS

NEWS

NIH SBIR/STTR will host Informational Webinars covering the FY18 Omnibus Release, Clinical Trials, and Electronic

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

NINDS Small Business Programs: Priorities

NOT-NS-18-002

- NINDS gives priority to **meritorious research proposals with the greatest potential to advance the NINDS mission**
 - We are especially interested in:
 - Novel and innovative technologies that are new to the SBIR or STTR programs.
 - Technologies coming to the SBIR or STTR programs for their first indication or market opportunity.
 - Companies and applicants that are new to the SBIR and STTR programs.
 - NINDS Cooperative Agreement (U44) Translational Programs.

<https://www.ninds.nih.gov/Funding/Small-Business-Grants>

NINDS Small Business Programs: Priorities

NOT-NS-18-002

Funding decisions are based on a combination of factors:

1. Potential for high impact on advancing the NINDS mission and the other programmatic priorities described in this Notice
2. Potential for commercialization
3. Portfolio balance (search NIH Reporter <http://projectreporter.nih.gov/reporter.cfm>)
4. Previous performance of the applicant and/or company in the SBIR/STTR programs
5. For Phase II applicants: the results of the Phase I
6. Peer review scores and critiques
7. Availability of funds

<https://www.ninds.nih.gov/Funding/Small-Business-Grants>

SBIR/STTR Tip

Focus on Investigator Initiated Research

- **NIH is generally not the final customer**
 - Customers are clinicians, researchers, caregivers, patients, etc.
 - Many technologies need additional funds or resources from investors/partners after Phase II to get to market
- **NINDS is focused on grants instead of contracts**
 - “Parent” SBIR/STTR Grant Solicitations ([PA-18-574](#)/[PA-18-575](#))
 - Where most of our funded applications are submitted
 - Company decides what market and product/service
 - Specific funding opportunities (<http://sbir.nih.gov>)
 - Not all of them have specific set-asides or separate reviews
 - Read funding opportunity carefully

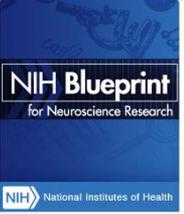
Keys to reading a Funding Opportunity Announcement (FOA)

- Different FOAs:
 - Program Announcement (PA)
 - PAR: special receipt, referral and/or review
 - PAS: set-aside funds
 - RFA: special receipt date, review, etc.
- Cooperative Agreement (U versus R mechanisms)
- Read Funding Purpose and Opportunity Description
- Budget requirements and years allowed
- Type of Applications allowed (e.g. Phase I, Phase II, Fast Track)
- Eligibility: Is it a small business mechanism?
- Application and Submission Information
- Review Criteria
- **Scientific/Research Contact(s) at the end**

NINDS Translational and Clinical Programs

Preclinical and Early Clinical Trials

Grants



Clinical Trials/ Infrastructure Resources

Grants



Many of these programs:

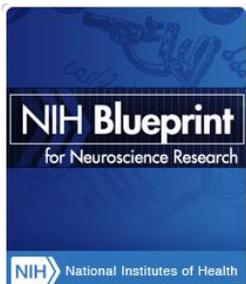
- Are milestone-drive
- Have SBIR Cooperative Agreement (U44)
- Have specific funding announcements

NIH Programs



Stimulating Peripheral Activity to Relieve Conditions (SPARC)

NINDS Cooperative Translational Programs



Small Molecules ([PAR-18-541](#)):

Charles Cywin, Ph.D. (charles.cywin@nih.gov)

- Cooperative agreement and SBIR Fast-Track award programs support small molecule drug discovery and development
- Access to consultants and contracts that provide discovery, preclinical development, and clinical trial support

Biologics ([PAR-17-457](#)/[PAR-18-543](#)):

Chris Boshoff, Ph.D. (chris.boshoff@nih.gov)

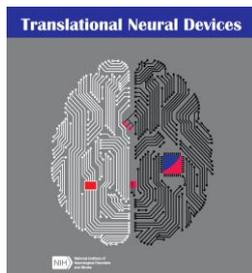
- Cooperative agreement and SBIR Fast-Track award programs support the discovery and development of therapeutic Biotechnology Products and Biologics (e.g. peptides, proteins, oligonucleotides, gene therapies, and cell therapies)
- Access to consultants



Neural Devices ([RFA-NS-18-012](#)):

Nick Langhals, Ph.D. (nick.Langhals@nih.gov)

- Cooperative agreement and SBIR Fast-Track award programs support development, validation and verification, and early clinical studies of therapeutic and diagnostic devices to treat neurological disorders.
- Support for small clinical trial to collect safety and effectiveness data



NINDS Biomarkers Initiative

Facilitate the development of high quality biomarkers to improve the quality and efficiency of clinical research

Analytical Validation - Biomarker measurement performance characteristics

[PAR-18-549](#)

- To encourage rigorous analytical validation of candidate biomarker measures or endpoints consistent with FDA guidelines.
- Evaluation of the assay, its performance characteristics, and the optimal conditions

Clinical Validation - Biomarker for use in clinical trials and/or clinical practice

[PAR-18-548](#)

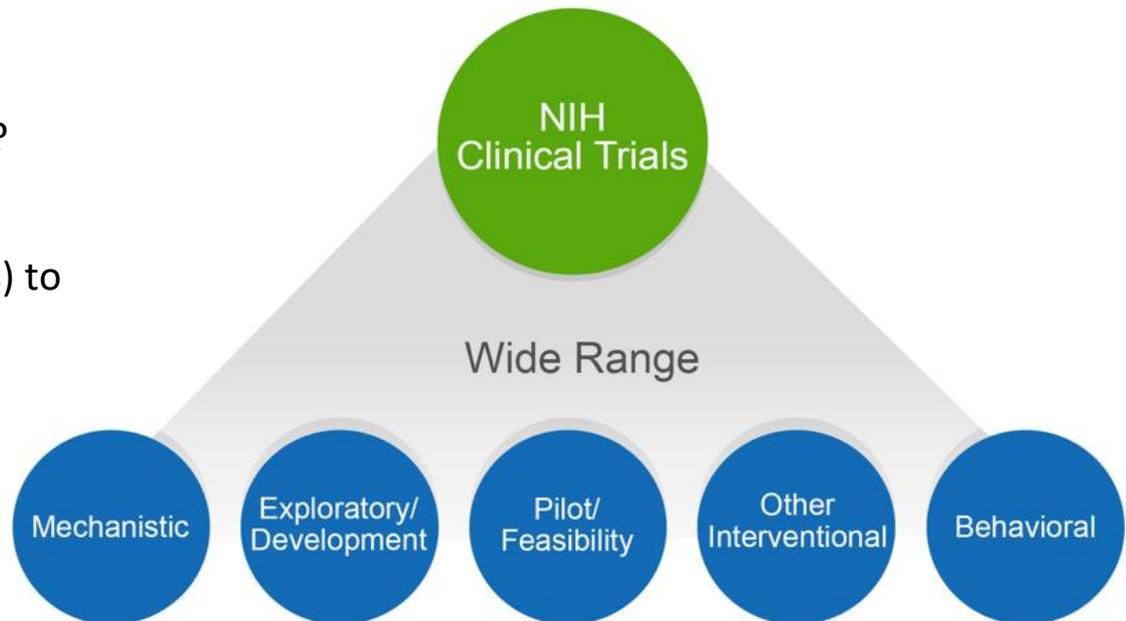
- To encourage rigorous clinical validation of a candidate biomarker using retrospective and/or prospective methods consistent with the purpose of the biomarker

Mary Ann Pellemounter, Ph.D. (mary.pellemounter@nih.gov)

NIH Definition of Clinical Trial

Does your study...

- ✓ Involve one or more **human subjects**?
- ✓ Involve one or more **interventions**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Have a **health-related biomedical or behavioral outcome**?



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

Unsure how to answer the questions? We have a tool that can help!

<https://grants.nih.gov/ct-decision/>

NIH Definition of Clinical Trial

Clinical Trials need to:

- ✓ Respond to a **clinical trial-specific FOA**
- ✓ Address additional **review criteria** specific for clinical trials
- ✓ **Register and report** clinical trial in ClinicalTrials.gov

**Due Dates on or after
January 25, 2018**

All clinical trial applications **MUST** be submitted to an FOA that allows clinical trials

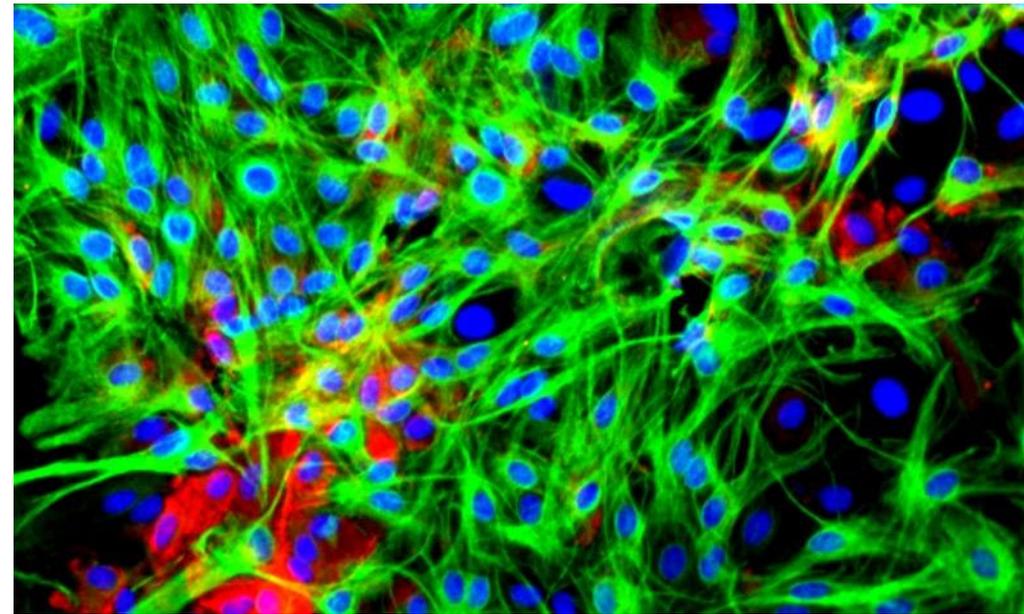
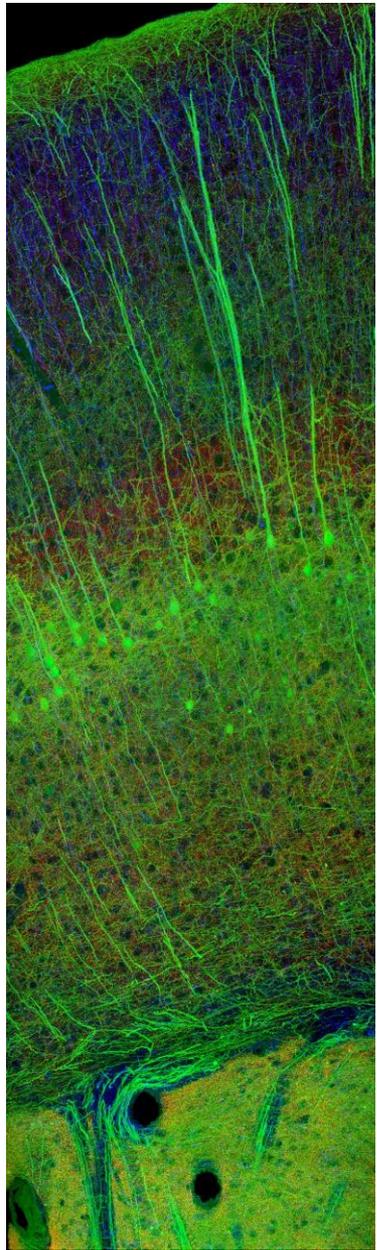
<https://grants.nih.gov/policy/clinical-trials/definition.htm>

NINDS Support for Clinical Studies

- Clinical Research (e.g. diagnostics) are accepted through the general solicitations (clinical trials not allowed)
- NINDS does NOT participate in the Clinical Trials SBIR/STTR omnibus solicitations
- Clinical Trials are accepted through specific program announcements (clinical trials optional or required)

<p>NINDS Exploratory Clinical Trials</p> <p>NINDS Renewal Awards of SBIR Phase II Grants (Phase IIB) Clinical Trials and Clinical Research</p>	<p><u>PAR-18-618 (SBIR)</u> <u>PAR-18-617 (STTR)</u></p> <p><u>PAR-18-665 (Phase IIB)</u></p>	<p>Stephanie Fertig <u>fertigs@ninds.nih.gov</u></p>
 <p>Neurology Network of Excellence in Clinical Trials</p>	<p><u>PAR-18-628</u></p>	<p>Codrin Lungu <u>lunguci@ninds.nih.gov</u></p>
 <p>StrokeNet Clinical Trials Network</p>	<p><u>PAR-18-628</u></p>	<p>Claudia Moy <u>moyc@ninds.nih.gov</u></p>

NIH BRAIN Initiative





Goal: See the neural circuits in action to understand:

- How the brain moves, plans, executes
- How to monitor/modulate circuits for improved function
- That disordered brain circuits cause neuro/mental/substance use disorders

Long-term goal: Make circuit abnormalities the basis of diagnostics, and normalization of circuit function the target of intervention

FIRST FIVE YEARS

Emphasize
technology
development

SECOND FIVE YEARS

Emphasize
discovery
driven science

<http://www.braininitiative.org/>

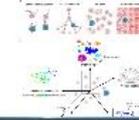
<https://braininitiative.nih.gov/>



The BRAIN Initiative®

BRAIN Update

BRAIN Publication Roundup – January 2018



Behavioral modeling and optogenetics elucidate mechanisms of subjective, history-dependent decision bias... Advanced transgenic approach improves lig...

Cell Type

Circuit Diagrams

Monitor Neural Activity

Interventional Tools

Theory and Data Analysis Tools

Human Neuroscience

Integrated Approaches

WHAT IS THE BRAIN INITIATIVE?

The Brain Research through Advancing Innovative Neurotechnologies® (BRAIN) Initiative is aimed at revolutionizing our understanding of the human brain. By accelerating the development and application of innovative technologies, researchers will be able to produce a revolutionary new dynamic picture of the brain that, for the first time, shows how individual cells and complex neural circuits interact in both time and space. Long desired by researchers seeking new ways to treat, cure, and even prevent brain disorders, this picture will fill major gaps in our current knowledge and provide unprecedented opportunities for exploring exactly how the brain enables the human body to record, process, utilize, store, and retrieve vast quantities of information, all at the speed of thought.

Highlights of The BRAIN Initiative®

News:

NIH BRAIN Initiative builds on early advances



2017 Funded Awards



BRAIN Initiative Funding Opportunities



Public Private Partnership program



Discover the BRAIN Alliance new Website



Job Opportunities



BRAIN 2025 Report

BRAIN Alliance

BRAIN Initiative Partners

Federal

National Science Foundation (NSF)

Defense Advanced Research Projects Agency (DARPA)

U.S. Food and Drug Administration (FDA)

The Intelligence Advanced Research Projects Activity (IARPA)

Non-federal

Foundations

Institutes

Universities

Industry

Small Business Opportunities

Development, Optimization, and Validation of Novel Tools and Technologies for Neuroscience Research

- For large scale recording/manipulation of neural activity
- To facilitate the detailed analysis of complex circuits and provide insights into cellular interactions

Supports iterative refinement with the user community to increase incorporation into regular neuroscience practice

[PAR-18-501](#) (SBIR)

[PAR-18-515](#) (STTR)

Next-Generation Invasive Devices for Recording and Modulation in the Human Central Nervous System

- Supports translational and clinical studies for invasive recording and/or stimulating devices to treat nervous system disorders and better understand the human brain
- Phased Translational-to-Clinical Research ([RFA-NS-18-021](#)- non SBIR/[RFA-NS-18-022](#) SBIR)
- Direct-to-Clinical Research ([RFA-NS-18-023](#))
- Utilize the NIH BRAIN Public-Private Partnership Program (*not required*)

Nick Langhals, Ph.D. (nick.Langhals@nih.gov)

BRAIN Public-Private Partnership Program

Program Goals: To facilitate partnerships between clinical investigators and manufacturers of the latest-generation **implantable stimulating and/or recording devices** for clinical neuroscience research in humans

- **Device companies have signed Memoranda of Understanding (MOU)** with the NIH to provide information on materials (devices, software, surgical tools, etc.) and support that each are willing to make available
- **Template Collaborative Research Agreements (CRAs)** have been developed to streamline agreements between academic institutions and commercial device manufacturers

https://braininitiative.nih.gov/Resources/BRAIN_PPP

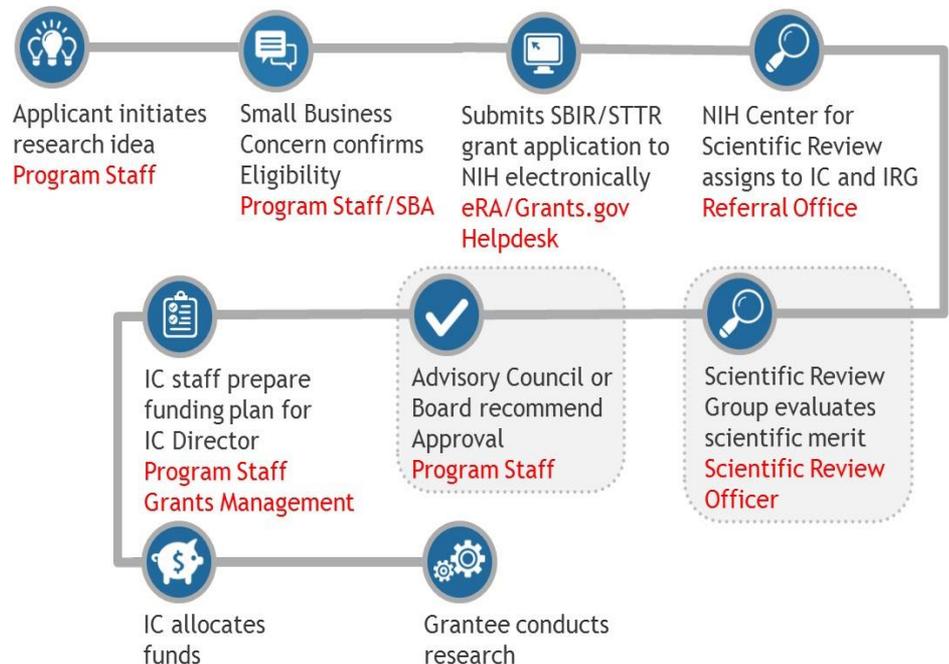
Important Facts to Remember

- Duplicative projects may not be submitted to NIH using different grant programs
- Applications **may be** submitted to **different agencies** for similar work to support different aims/objectives
- Awards may not be accepted from different agencies **for duplicative projects**

SBIR/STTR Tip

Understanding Peer Review is Critical

- NIH reviews applications with panels made up of outside experts
- Most applications are reviewed at the Center for Scientific Review (CSR)
 - Scientific Review Officer sets up the panel and runs review
 - Review panels look at grants from multiple Institutes/Centers
- Score can decide if you will be considered for funding (or not)
- Budget is not “scorable” - a smaller project budget does not mean a better chance of being funded



<https://www.csr.nih.gov> has useful information about review for new applicants



Common Application Problems



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

SBIR/STTR Tip

Be Prepared to Resubmit



“SBIR is a tough route, and people should be aware of that. The reviewers are not concerned about feelings. But take the criticism seriously, correct the things that need correcting and be prepared to resubmit. Don’t give up because of a depressing review.”



Mary Potasek, Ph.D.

President and Co-founder
Simphotek

Talk to your Program Officer:

- Before Submission (there are NO stupid questions)
- After receiving the summary statement (regardless of how you did)
- **WE CAN HELP YOU!**

Beyond SBIR/STTR grants

Pre-SBIR/STTR:

Entrepreneurial Assistance/ Training
NIH I-Corps™ (pilot) and C3i Programs

Applicant Assistance Program
For new/unsuccessful applicants

Phase I:

Market Analysis:
Niche Assessment Program (NAP)

Entrepreneurial Assistance/ Training
NIH I-Corps™ and C3i Programs

Phase II/IIB:

Technical Assistance/Training:
Commercialization Accelerator
Program (CAP)

More information:

<https://www.ninds.nih.gov/Funding/Small-Business-Grants/Entrepreneurial-Resources>



Partnering Opportunities:
Sponsored/Discounted Attendance
at Events/Conferences and
Pitch Coaching

Applicant Assistance Program (AAP)

NOT-CA-18-031

- Eligibility:
 - Companies who have not previously won an SBIR/STTR award from NIH
 - No current grants pending peer review
 - Phase I applications only
 - NCI, NINDS or NHLBI mission
- Free Services:
 - Needs Assessment/Small Business Mentoring
 - Phase I Application Preparation Support
 - Application Review
 - Team/Facilities Development
 - Market Research
 - Intellectual Property Consultation
- Encourage participation: women-owned businesses, socially/economically disadvantaged small businesses, small businesses in under-represented states

<https://www.dawnbreaker.com/aap>

- Save the Date -

20th Annual HHS SBIR/STTR Conference



October 30 - November 1, 2018
Dallas, Texas

Stay connected for updates!
@NIHsbir | <https://sbir.nih.gov/>

**READ program announcements carefully
CONTACT a Program Officer before applying**

Stephanie Fertig, Director NINDS Small Business Programs

fertigs@ninds.nih.gov

**Natalie Trzcinski, Health Program Specialist, NINDS Small Business
Programs**

natalie.trzcinski@nih.gov



@NINDStranslate

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