

America's Seed Fund is Open for Business

Rob Vinson (Moderator)
Stephanie Fertig, MBA





America's Seed Fund is Open for Business

Stephanie Fertig, MBA

**HHS Small Business Program Lead, SEED (Small business Education & Entrepreneurial Development)
Office of the Director | Office of Extramural Research | National Institutes of Health**



To enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.



National Institutes of Health
SBIR and STTR \$1.2 billion



Centers for Disease Control and Prevention
SBIR \$12 million



Food and Drug Administration
SBIR \$2 million



Administration for Community Living
SBIR \$3 million



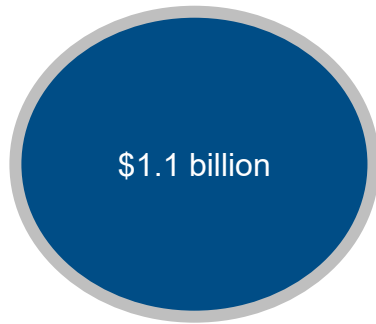
*To seek fundamental knowledge about the nature and behavior of living systems and the **application of that knowledge to enhance health, lengthen life, and reduce illness and disability.***

The Small Business Program helps NIH accelerate discoveries from bench to bedside



Congressionally Mandated Programs

\$1.2 Billion Dedicated Funding via Set-aside from NIH's R&D Budget



SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

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



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



Since SBIR is a bigger program, I have a better chance of getting an SBIR awarded.

Myth Busted

The size of the program does not correlate with the chance of getting an award.

For example, smaller programs (i.e. STTR) or NIH Institutes may have far fewer applications.



It is easier (and better) for a company to just get investors and avoid all the work and time to apply for an NIH grant!

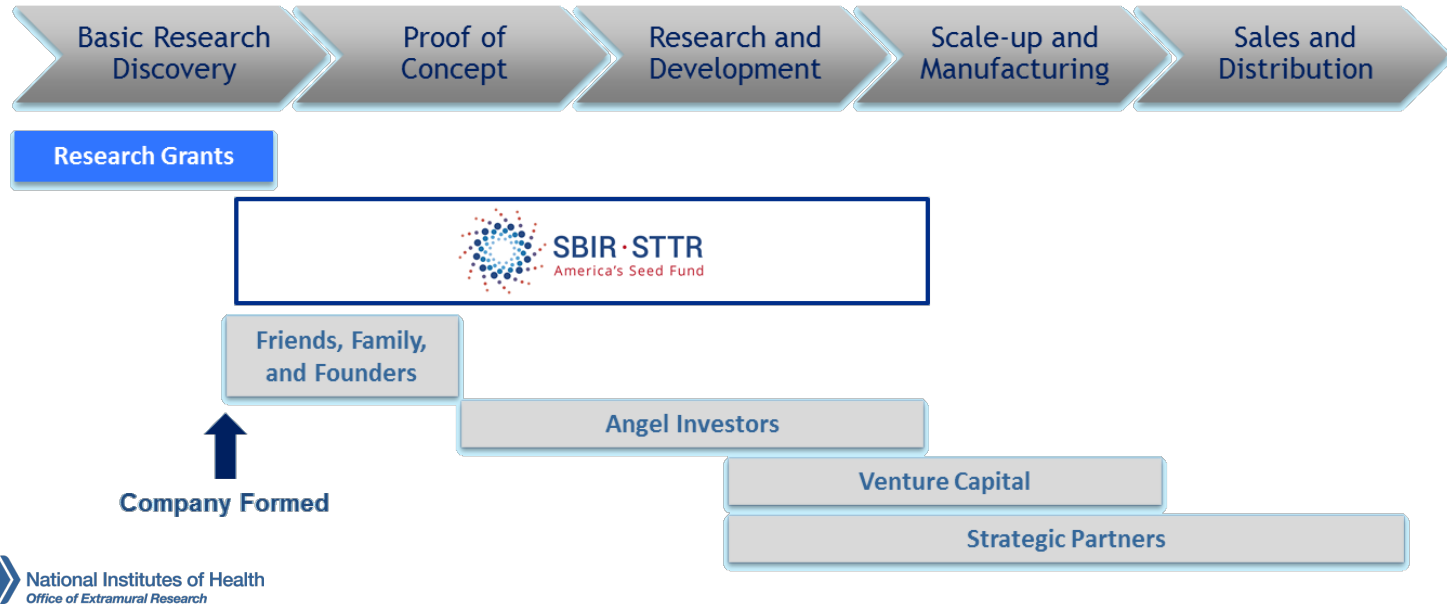
Myth Busted

Companies that have developed their product with non-dilutive small business program money are very attractive to investors and strategic partners.



The largest sources of early-stage capital for life sciences in the US

- **“Free Money”**- Non-dilutive capital and not a loan
- **Data and intellectual property rights** are protected
- Awardees can **leverage funding** to attract investors and partners



Small Business Success Stories

Small Business Success Stories

The NIH is actively turning discovery into health by helping small businesses develop innovative technologies that improve health and save lives.

Technology

- ☐ Diagnostic
- ☐ Digital Health
- ☐ Drug
- ☐ Medical Device
- ☐ Research Tool

Development Stage

- ☐ Approved for Use
- ☐ Early Development
- ☐ Human Testing

Company Ownership

- ☐ Woman Owned
- ☐ Minority Owned

State

Select State

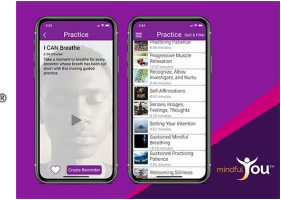


Displaying results 1 to 10 of total 66

Results per page 10

Company	Story	State - District ¹
Cell Podium, LLC	Video Messages Sent Directly to Cell Phones Improve Public Health During Crises	NJ - 6
Advanced Circulatory Systems	A Life-Threatening Experience Inspires Enhanced CPR	MN - 4
Cognition Therapeutics	Alzheimer's Drug Shows Progress in Restoring Cognitive Function	PA - 18

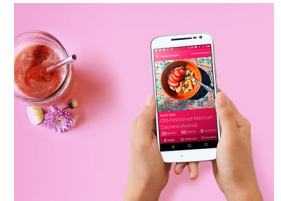
Digital Learning Company Supports Parents, Teachers, and Underserved Communities



Latina-Owned Business Creates Effective Public Health Campaigns



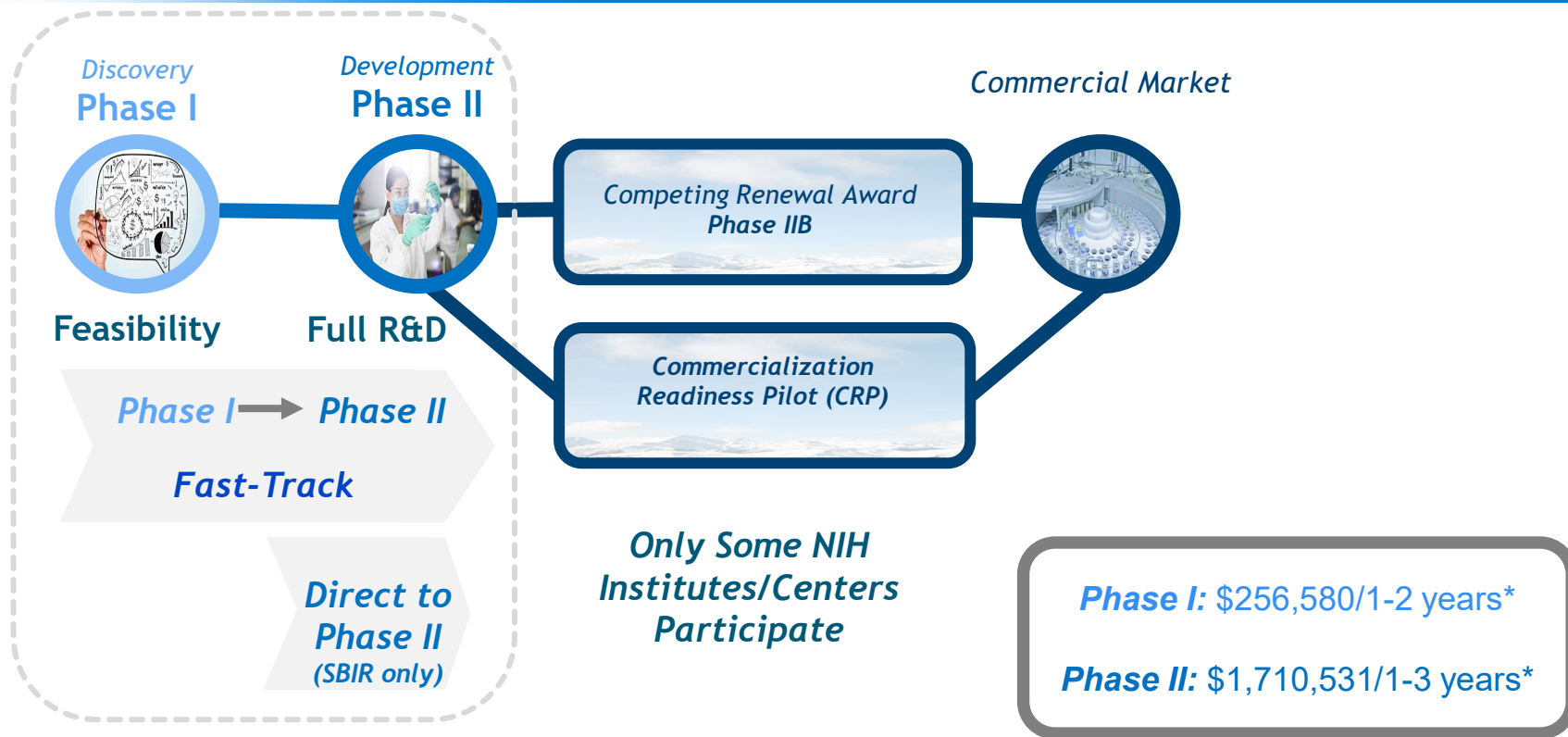
De las mías™
Unidas for a healthy life.



sbir.nih.gov/stories



Phased Programs



It is much harder to get a NIH Fast-Track or Direct to Phase II, so don't even bother applying for those

Myth Busted

Although the majority of new projects (74%) are Phase I, we support many Fast-Tracks and Direct to Phase II. Speak with a program officer to determine the best path for your project



The SBIR/STTR budget cap is too small to be useful. It is not worth the time or money!

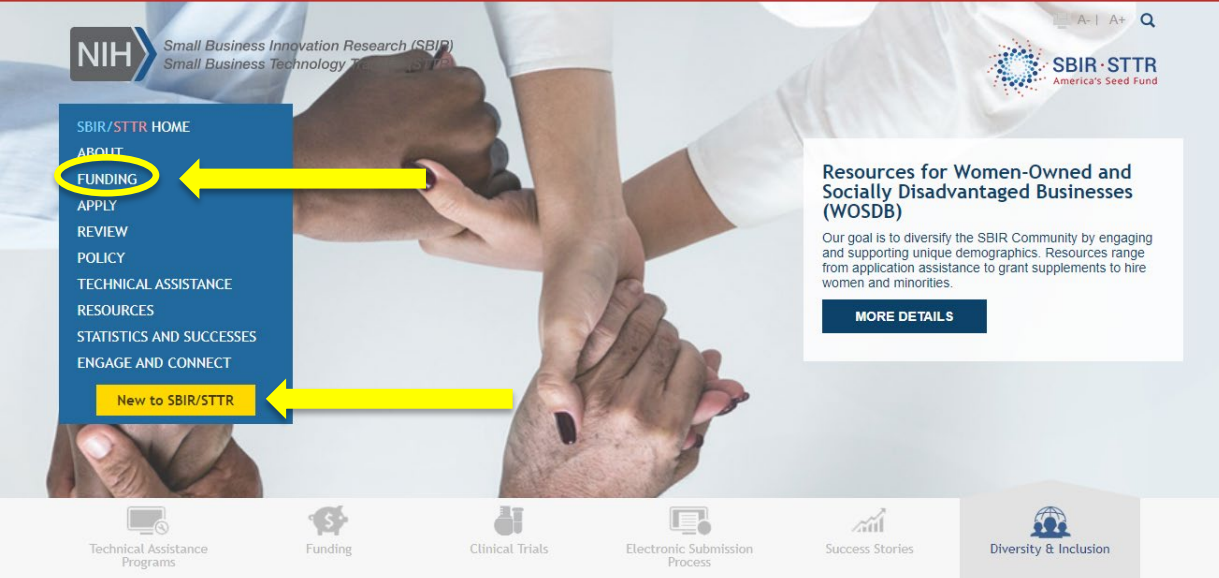
Myth Busted

NIH can exceed the SBIR/STTR budget guidelines for many topic areas. A list of approved topics is published every year at <https://sbir.nih.gov/funding>.



Coronavirus 2019:

Information for NIH Applicants and Recipients
Small Business Relief Options and Resources (SBA)



<https://sbir.nih.gov>

Omnibus (General) Solicitations and Targeted Funding Announcements

Standard receipt dates*:
September 5, January 5,
April 5

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

HHS SBIR/STTR COMPONENT PROGRAM LINKS



*Targeted Funding Announcements
may have different receipt dates

Novice applicants to the program are almost never successful at getting awards.

Myth Busted

25% of all SBIR and STTR awards last year went to new investigators.

NIH strongly encourage new applicants - particularly from under-represented innovators or parts of the country.

NIH Applicant Assistance Program:

<https://sbir.cancer.gov/programseducation/aap>



I should apply to a specific program announcement because targeted funding opportunities have their own dedicated funding.

Myth Busted

Most NIH awards (79%) are made to applications submitted to the omnibus (general) solicitations.

Not all targeted program announcements have special set-asides.



My project is low risk and only has a few human subjects so it is not a clinical trial.

Myth Busted

The NIH definition of a clinical trial is not the same as the FDA's and is not based on risk or number of subjects.

Not all NIH Institutes accept applications with clinical trials, so it is important to talk with a program officer!



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

Clinical Trial Requirements for Grants and Contracts

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

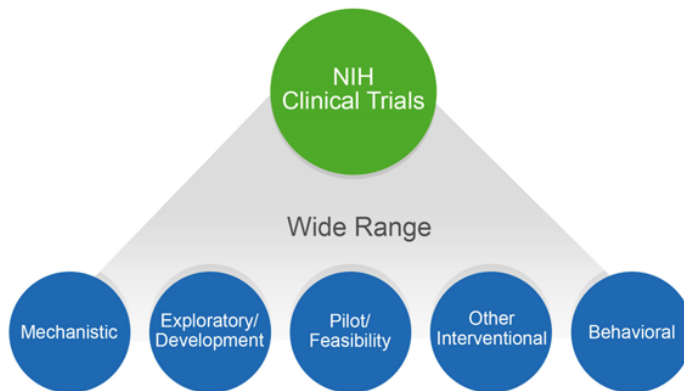
NIH Definition of a Clinical Trial

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

DECISION TOOL

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

FIND OUT HERE



Applications are submitted to a specific Institute, so I need to choose the Institute and Study Section for my application.

Myth Busted

Applications are submitted to NIH and then assigned to a specific Institute and Study Section. You can request a specific Institute or Study Section but you don't have to!



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>



My application didn't get discussed or funded the first time. It's a waste of time to try again.

Myth Busted

Many companies are funded after incorporating feedback into their resubmission.

Read the summary statement carefully and contact your program officer to discuss. Offer to be a reviewer.



The Small Business Programs only provide money.

Myth Busted

The Small business Education and Entrepreneurial Development (SEED) Office provides technical and business assistance, education, partnering/investment opportunities, and commercialization support.



New Support for Awardees

Technical and Business Assistance (TABA)

TABA Needs
Assessment



TABA Funding
(requested in grant application)

Education

I-Corps at NIH *Phase I

Concept to Clinic:
Commercializing Innovation
(C3i) Program

Funding and Support

CRP Funding *Phase II/IIB

Regulatory & Business
Development Consultants

Partnering and Investment Opportunities

Company Showcase



REDEFINING
EARLY STAGE
INVESTMENTS



NIH National Institutes of Health
Office of Extramural Research

<https://sbir.nih.gov/support-for-awardees>

Finance, Strategy, Intellectual Property, Regulatory Experts



Investor-in-Residence



Entrepreneurs-in-Residence



Intellectual Property



Regulatory/Reimbursement



NIH bureaucrats are unapproachable and I should minimize my discussions with them.

Myth Busted

The SEED Office and NIH program officers, scientific review officers, and grants managers are here to help!



Most Important Piece of Advice

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

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

SBIR/STTR Home > Engage & Connect > IC Program Contacts

Contact

- Contact SBIR/STTR
- IC Program Contacts
- eRA Service Desk (for electronic submission Qs)
- Connect

Engage

- Twitter
- Listserve
- News
- Webinar
- Events

Questions? Use the NIH PDF Version

/Grants Mgmt Contact

reza
01-402-7739
sle.perez@nih.gov

National Institute on Alcohol Abuse and Alcoholism http://www.niaaa.nih.gov	Megan Ryan Phone: 301-443-4225 Email: mryan1@mail.nih.gov	Jeff Thurston Phone: 301-443-9801 Fax: 301-443-3891 Email: jeffrey.thurston@nih.gov
National Institute of Allergy and Infectious Diseases http://www.niaid.nih.gov	Natalia Kruchinin Phone: 240-669-2919 Fax: 240-627-3162 Email: kruchinin@niaid.nih.gov	Vandhana Khurana Phone: 240-669-2966 Fax: 301-493-0597 Email: khuranav@niaid.nih.gov

Talk to a Program Officer at least a month before the application deadline!

List of SBIR Program Managers:

<https://sbir.nih.gov/engage/ic-contacts>

Research Portfolio Online Reporting Tools (RePORT): <https://report.nih.gov/>

Not sure who to contact?

<https://public.era.nih.gov/commons/public/serviceDesk/initseed.era>

or

Email: SEEDinfo@nih.gov



Get Connected

Subscribe to the
SBIR/STTR Listserv



@NIHSEED 

NIH Guide for Grants
and Contracts
(weekly notification)



Read our NIH SBIR/STTR
Success Stories



Follow SEED



Connect with Us


<https://seed.nih.gov>
[v
https://sbir.nih.gov/](https://sbir.nih.gov/)



SEEDinfo@.nih.gov

