





Innovator to Entrepreneur Program (ITEP) NIAID SBIR/STTR Program Information Webinar

January 7, 2025





Webinar Housekeeping

- Please make sure your microphone is muted and your camera is off.
- If you have questions during the presentation, please type them in the Q&A.
- We will answer as many questions as time allows at the end of the presentations. A transcript with the questions and answers will be sent to all registrants.







National Institute of Allergy and Infectious Diseases (NIAID), NIH



Innovator to Entrepreneur Program (ITEP) NIAID SBIR/STTR Program Information Webinar

Matt Gibbons
Small Business Development Specialist
Small Business Program, NIAID, NIH

January 7, 2025





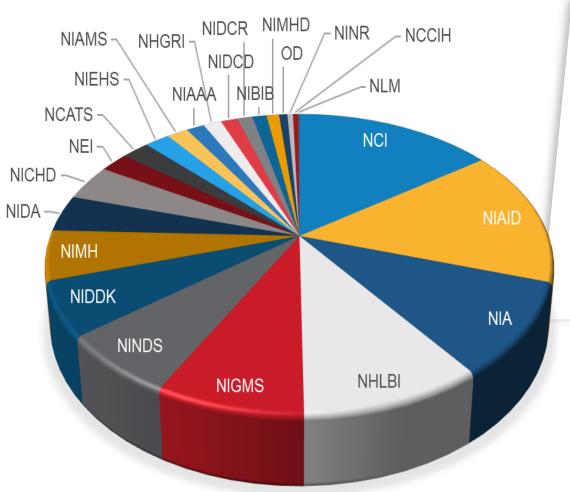
NIAID's Mission Statement

- NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.
- NIAID has a unique mandate that requires the Institute to respond to emerging public health threats.
- NIAID's three extramural divisions are the Division of AIDS (DAIDS); Division of Allergy, Immunology, and Transplantation (DAIT); and Division of Microbiology and Infectious Diseases (DMID).





NIH SBIR/STTR Budget Allocation FY24



NIH SBIR/STTR Budget \$1.347 B

NIAID SBIR/STTR Budget \$195.2 M





NIAID SBIR/STTR Program at Glance

- Waiver Policy Phase I: \$300K/year for up to 2 years; Phase II: \$1M/year for up to 3 years
 - Topics are interpreted broadly by NIAID Program Officers.
 - Does not impact funding decision (may be reduced if needed)
- NIAID allows Phase IIB applications via the SBIR Parent and select notices of funding opportunity (NOFOs).
 - Matching funds encouraged (not required)
 - SBIR only (Phase II STTR awardees can switch)
- NIAID only accepts SBIR Clinical Trial applications through its U44 mechanism (PAR-24-099).
 - Phase II/IIB, Fast-Track, and Direct-to-Phase II
- NIAID participates in the Commercialization Readiness Pilot (CRP) Program via PAR-23-219 (SB1, Clinical Trials Not Allowed) only.
- NIAID funds applications primarily based on Scientific Merit (i.e., Priority Score).
 - All applications (except CRP, U44) within published paylines are funded.





No-Cost Entrepreneurial Training: NIAID Innovator to Entrepreneur Program(ITEP)

- ITEP will assist participants in making the transition from innovator to first-time entrepreneur by providing cohort-based, no-cost training in entrepreneurship, startup operations, and grantsmanship
- NIAID will support two ITEP cohorts of up to 22 participants in the inaugural year.
- ITEP will emphasize support for applicants from underrepresented groups

ITEP Point of Contact:

Kenneth Kim

kenneth.kim2@nih.gov





No-Cost Grantsmanship Training: NIAID Small Business Applicant Assistance Program (AAP)

- AAP offers assessment, coaching, proposal development assistance, and post-submission support for Phase I and Phase II/IIB applicants
- AAP goals are to improve the quality of applications and to increase accessibility for underrepresented entrepreneurs and investigators
- AAP's cycles provide proposal development support for the grant due dates
- Subscribe to our <u>ListServ</u> to stay in the loop!







AAP Point of Contact:
Hejiao English
hejiao.english@nih.gov





- NIAID SBIR/STTR website <u>www.niaid.nih.gov/grants-contracts/small-businesses</u>
- NIAID SBIR/STTR High-Priority Areas of Interest
 - *NIAID would primarily consider applications that align strongly with NIAID's mission/priorities. www.niaid.nih.gov/grants-contracts/areas-interest-small-business
- NIAID Current Small Business Funding Opportunities
 www.niaid.nih.gov/grants-contracts/opportunities?f%5B0%5D=grants%3A131
- NIH SBIR office: "Samples of SBIR/STTR applications from NIAID are one of our most requested resources."
 www.niaid.nih.gov/grants-contracts/sample-applications#r43r44





Most Important Piece of Advice

- Call or send an email to the NIAID Program Officer for feedback on your application before submission. Program Officer contact information can be found on the <u>HHS</u> <u>Agency Contact webpage</u>.
 - NIAID: Dr. Natalia Kruchinin (NIAID Small Business Program Coordinator), kruchininn@niaid.nih.gov

or

- NIAID SBIR/STTR: <u>NIAIDSBIR@mail.nih.gov</u>
- Please include a non-confidential abstract of your technology and planned specific aims for your future project.
- SUBMIT EARLY (days, not hours and minutes)!











Thank you!

Matt Gibbons
Small Business Development Specialist
Small Business Program, NIAID, NIH







Innovator to Entrepreneur Program (ITEP) The Innovation and Commercialization Office: Small Business (SBIR/STTR) Programs

Yasamin Moghadam, MS

Scientific Program Specialist
Innovation and Commercialization Office
Division of Extramural Research Activities
National Heart, Lung, and Blood Institute (NHLBI)



I&C Mission

Improve probability of NHLBI-funded technologies impacting patients

Lead training and educational programs for HLBS innovators

Goals

Broaden diversity, inclusion, and reach of the small business program

Create novel solutions to meet unmet HLBS needs

MISSION

To accelerate the translation of discoveries and innovations into new biomedical products and services for heart, lung, blood and sleep diseases and disorders

VISION

Development of a biomedical community that rapidly commercializes heart, lung, blood, and sleep technologies to improve public health



NHLBI Mission Space



Heart

- Arrhythmias
- Atherothrombosis
- Chronic Heart Failure
- Congenital Heart Defects
- Coronary Artery Disease
- Hypertension

Lung

- ARDS
- Asthma
- Chronic Obstructive Pulmonary Disease
- Cystic Fibrosis
- Fibrotic Lung Disease
- Pulmonary Hypertension





Blood

- Bleeding Disorders
- Anemia
- Myeloproliferative Disorders
- Sickle Cell Disease
- Thrombotic Disorders

Sleep

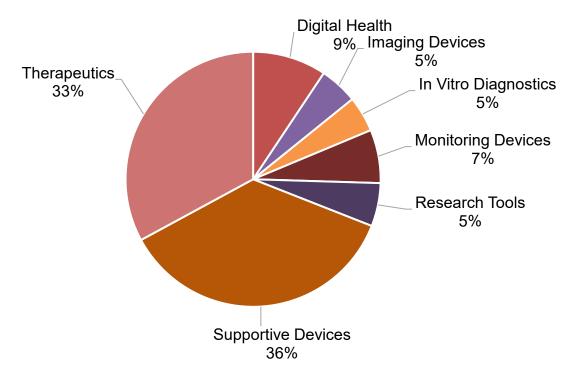
- Circadian Disorders
- Insomnia
- Obstructive Sleep Apnea
- Sleep-Disordered Breathing



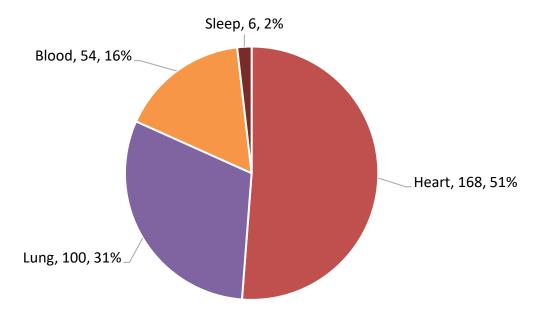
The NHLBI Small Business Program

Innovative and commercially-promising products to prevent, treat and diagnose heart, lung, blood, and sleep (HLBS)-related diseases

Technologies Funded by the NHLBI SBIR/STTR Program



Scientific Classification of Funded Projects





NHLBI I&C Programs and Services & Timing

APPLICATION SERVICES

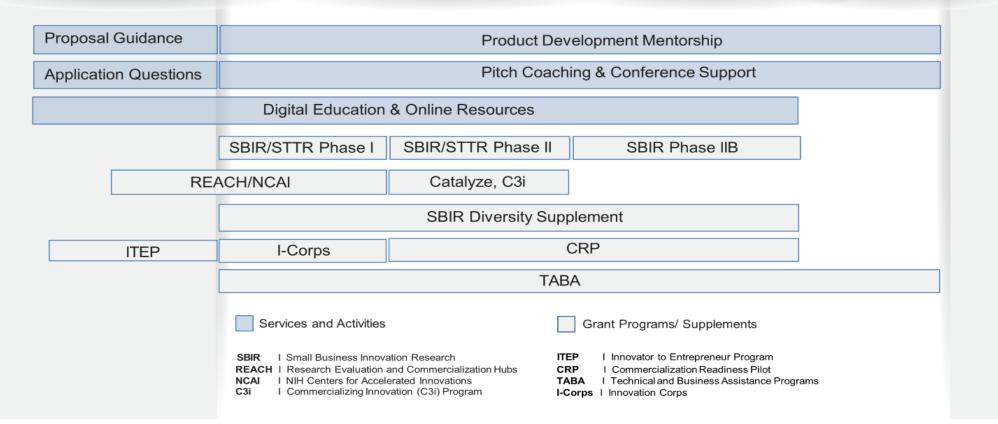
SMALL BUSINESS PROGRAM (SBIR/STTR)
& AWARDEE OPPORTUNITIES

Basic & Early-stage Translational Research Proof of Concept

Research & Development

Regulatory, Scale-up, and Manufacturing

Sales & Distribution



Adoption by Patients & Providers

Public Health & Social Impact

Advisory Experts at NHLBI

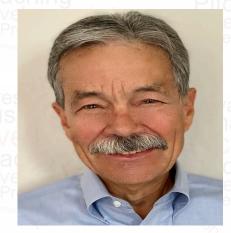
Renée Arnold



Entrepreneur in Residence

Health Economics
Outcomes Research
&
Reimbursement

Steve Flaim



Investor-In-Residence

Investing

Kwame Ulmer



Entrepreneur in Residence

Regulatory

Kimberly Martin



Entrepreneur in Residence

Clinical Trials

John Hsu



Entrepreneur in Residence

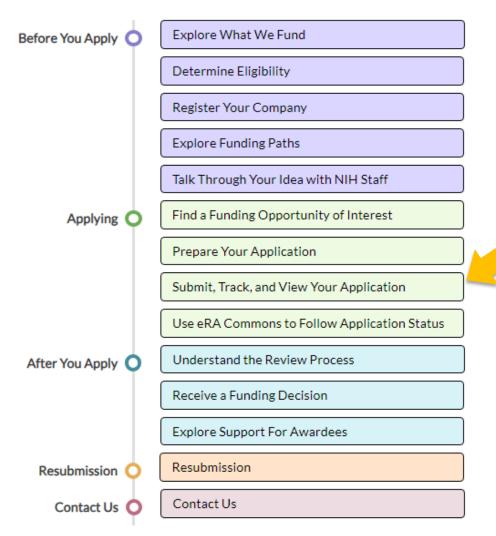
Intellectual Property



Resources to Apply for an SBIR/STTR Grant

Resources

https://seed.nih.gov/small-business-funding/how-to-apply



Links to:

Application Instructions
Annotated Form Set
Sample Applications

Programs for Applicants:

- NIH Applicant Assistance Program
- Health Disparities Pre-Application (HDPreAPP) Program

https://seed.nih.gov/aboutseed/diversifyentrepreneurial-workforce

Connect with Us!

 Follow us on Twitter at @NHLBI_SBIR

 Email us at <u>NHLBL_SBIR@mail.nih.gov</u>

Visit the I&C Website



Sign up for our I&C Newsletter











Innovator to Entrepreneur Program (ITEP)

Informational Webinar



Konstantin Izvolsky, Ph.D.

Director of Consulting and Training
Foresight Science & Technology, Inc.

January 7, 2025



Presentation Overview

ITEP Overview and Eligibility

 Foresight Science and Technology- Your ITEP Content Provider

ITEP Structure

ITEP Workflow and Key Dates

Next Steps

SBIR/STTR Program

- Set aside program based on extramural research budget of agencies.
- Designed to stimulate R&D, innovation and commercialization of new technologies to meet the needs of the public (Grants) and Federal Agencies (Contracts).

• It is a well-known fact that participation in entrepreneurship has significant racial and socio-economic barriers. SBIR/STTR programs work diligently to address this disparity.

ITEP Overview

- The National Institute of Allergy and Infectious Diseases (NIAID) and the National Heart, Lung, and Blood Institute (NHLBI) established Innovator-to-Entrepreneur Program (ITEP) providing participants with entrepreneurship and SBIR/STTR grantsmanship training.
- ITEP benefits inventors developing innovative products that align with NIAID/NHLBI interests who have no history of prior success in SBIR/STTR, and little to no experience in entrepreneurship.

ITEP Overview

• ITEP has an emphasis on engaging and assisting groups underrepresented in extramural biomedical small business programs.

• ITEP may be of particular interest to organizations promoting innovation and entrepreneurship among minorities, women, and socially disadvantageous groups.

ITEP Eligibility

To be eligible for the program, participants must meet the following criteria:

- Be an individual inventor or represent the established small company.
- Develop or plan to develop products that are within the scope of NIAID and NHLBI areas of interest.
- Have little to no previous experience in entrepreneurship.
- Have not previously received an SBIR/STTR award.

ITEP Goals and Objectives

 Assist participants in the transition from innovator to entrepreneur.

• Equip participants with the knowledge necessary to launch their companies, develop products and establish appropriate business strategies.

 Provide aspiring inventors and early-stage entrepreneurs with the skills and confidence to successfully tackle the NIAID/NHLBI SBIR/STTR application process.

Foresight Science & Technology: Your ITEP Content Provider

• Small-business consulting company headquartered in Massachusetts.

 Subject matter expertise: 60 Senior Consultants with expertise across all industries.

Deep understanding of SBIR/STTR programs.

Foresight Science and Technology: Commercialization Training Services

 World-leading full-service provider of commercialization and entrepreneurship training and grantsmanship services for clients including government agencies, companies, laboratories, foundations, and universities.

• Expertise in delivering training content to audiences with various levels of commercialization expertise: from early-stage innovators to established companies.

Foresight Science & Technology: Supporting NIH SBIR Programs

 More than 15 years of providing commercialization support to NIH SBIR/STTR awardees.

• In-depth understanding of SBIR/STTR programs, the needs of SBIR/STTR awardees and preparation of technical/scientific sections of their proposals.

Foresight developed training curriculum covering topics necessary to understanding the technology commercialization process and SBIR/STTR Program.

Topics include:

- Starting a Strong Business and Creating a Business Story
- Protecting Your Idea (IP and University Spinouts)
- Defining Your Product, Business Model, Market, Customer and Developing Business Strategies
- Deep Dive in SBIR/STTR Program and Specifics of NIH SBIR/STTR Application Process
- Complexities of Health Technologies Development
- Startup Financing and Taking Business Forward

• Two cohorts, up to 22 participants each (Winter and Summer).

 Curriculum will be delivered via 14 weekly live webinars presented by the team of Foresight consultants.

All webinars will be recorded and available online.

• Training for Winter cohort begins February 12, 2025.

• Webinars will be combined with one-on-one training with Foresight consultants (Mentors).

 One-on-One training will be tailored to the needs of specific program participants. Schedule and the mode of communication is determined by participant and Mentor.

 The goal of this training is to prepare an individual virtual presentation that includes plans and provisions to apply for NIAID/NHLBI SBIR/STTR funding.

- Final Presentations will be delivered after the end of Oneon-One training (end of May 2025).
- The Final Presentation is a pitch of a mock business plan for the technology within the area of NIAID/NHLBI interests.
- Presentations are expected to include:
 - Technology Value Proposition
 - Competitive Intelligence Information
 - Market Information
 - IP Information
 - Revenue Model and Revenue Projections
 - Team And Resources Information

ITEP Workflow and Key Dates

Promote Sign Up Webinars One –on-one Training Survey & Report

- NIAID and NHLBI promote the program and the informational webinar via email
- Informational Webinar: January 7, 2025
- Foresight is developing the curriculum and training content

- ITEP Application Period opens: January 8, 2025 at 12pm ET
- Application link goes live
- First come-first served
- Qualified participants are notified by Foresight

- Webinars begin: February 12, 2025
- 14 live weekly webinars (every Wednesday 3.30-5pm ET)
- All webinars will be recorded and available to program participants
- Attending live webinars is strongly recommended

- One-on-one training begins: February 26, 2025
- One-on-one training will solidify participant understanding of curriculum and prepare them for the final presentation
- Final
 Presentations:
 End of May 2025

- After the training is complete:
- Foresight sends a survey to participants upon completion of training. For each participant Foresight will develop and Endof-Project summary
- Completed surveys are sent to NIAID and NHLBI to improve the quality of the program

Success of ITEP

Always prepared:

- Review areas of <u>NIAID</u> and <u>NHLBI</u> interest
- Get basic understanding of SBIR/STTR programs (https://seed.nih.gov/NIAID home)
- Get basic understanding of technology commercialization process (Foresight Street: <u>youtube.com/user/ForesightSciTech</u>)

Next Steps

• ITEP application form will open on January 8, 2025 at 12pm ET.

Please visit
 <u>https://www.cognitoforms.com/foresightsciencetechnologyinc/niaidnhlbiinnovatortoentrepreneurprogramitep</u>

Enrollment is ongoing until Winter 2025 cohort is filled.

Thank You!

Konstantin Izvolsky, Ph.D.

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Questions

Please submit questions in the Q&A, and we will answer as many as we can during the time remaining.

A transcript with all of the questions and answers during this webinar will be prepared and shared with registrants.



