

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



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

Kenneth Kim, MS Small Business Development Specialist Small Business Program, NIAID, NIH

**December 6, 2023** 





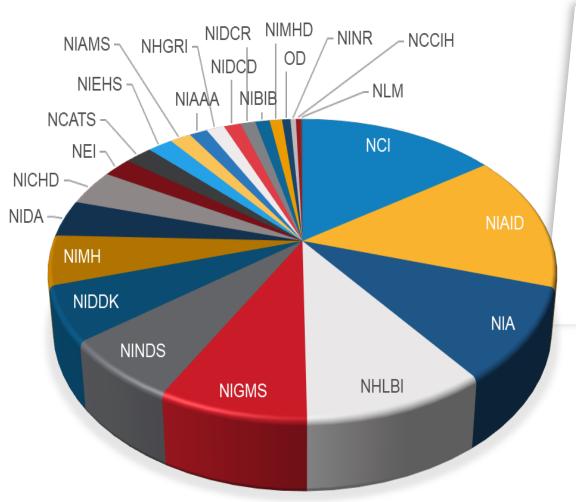
#### **NIAID's Mission Statement**

- 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 FY23



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-21-082).
  - 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 www.niaid.nih.gov/grants-contracts/small-businesses
- 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!

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# 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
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

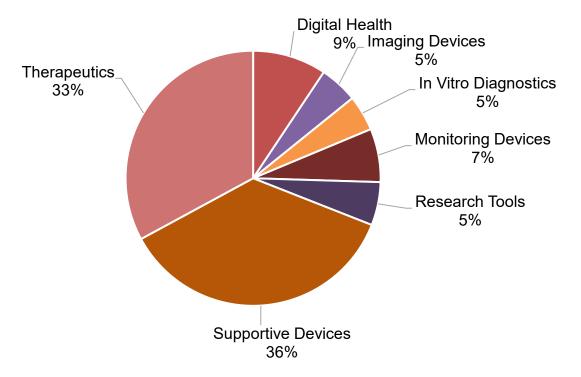
- Circadian Disorders
- Insomnia
- Obstructive Sleep Apnea
- Sleep-Disordered Breathing



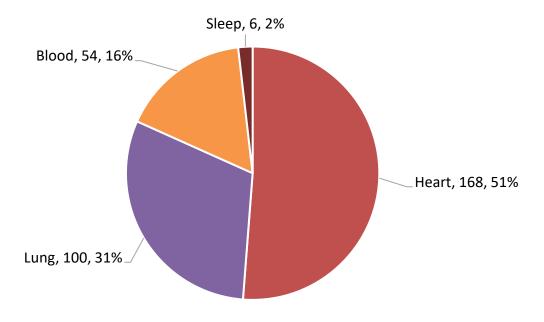
## The NHLBI Small Business Program

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

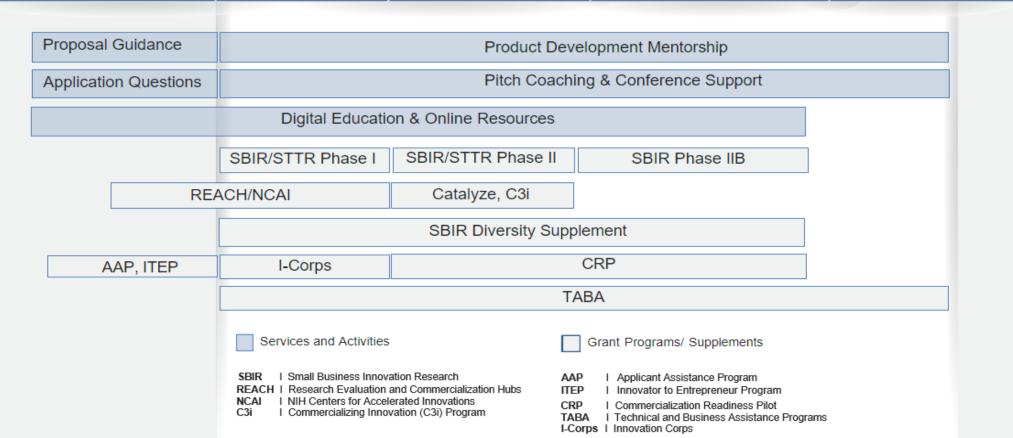
SMALL BUSINESS PROGRAM (SBIR/STTR)
& AWARDEE OPPORTUNITIES

Basic & Early-stage Translational Research Proof of Concept

Research & Development

Regulatory, Scale-up, and Manufacturing

Sales & Distribution



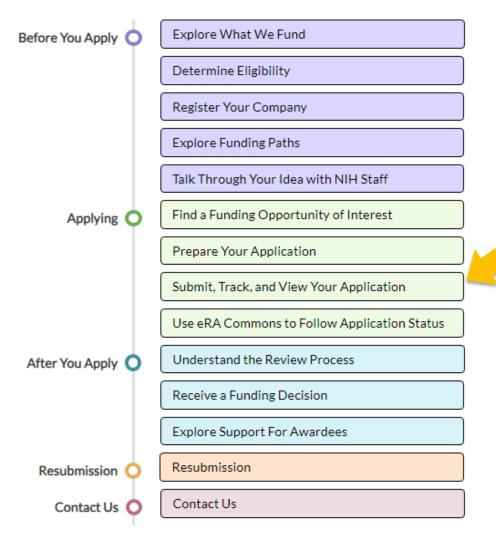
Adoption by Patients & Providers

Public Health & Social Impact

## 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.

December 6, 2023



## Presentation Overview

• ITEP Program 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.

## NIAID/NHLBI Innovator to Entrepreneur Program Overview

- The National Institute of Allergy and Infectious Diseases
   (NIAID) and the National Heart, Lung, and Blood Institute
   (NHLBI) established this program for inventors and early stage entrepreneurs, providing them with entrepreneurship
   and SBIR/STTR grantsmanship training.
- ITEP will benefit inventors developing innovative products that align with NIAID/NHLBI interests who have no prior experience in SBIR/STTR grantsmanship, and little to no experience in entrepreneurship.

## NIAID/NHLBI Innovator to Entrepreneur Program 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.

## Program Eligibility

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

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

# Foresight Science & Technology: Your ITEP Service 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 technology transfer, commercialization, entrepreneurship training, due diligence, 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 the needs of SBIR/STTR awardees, and preparation of technical/scientific sections of their proposals.

• The experience in drafting compelling commercialization plans necessary to bring new technologies to market.

## ITEP Goals and Objectives

 Assisting participants in the transition from innovator to entrepreneur.

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

 Upon completion, participants will be equipped with the knowledge to launch their company and apply for the NIAID/NHLBI SBIR/STTR grants.

The training curriculum will cover topics necessary to understanding the SBIR/STTR Program and technology commercialization process.

#### Topics include:

- Building a Strong Business and Creating your Business Story
- Protecting Your Idea
- Search for Equity Funding
- SBIR/STTR Program Overview
- Specifics of NIH SBIR/STTR Program
- SBIR/STTR Compliance and Award Management
- Complexities of Health Technologies Development

 Material will be delivered via weekly live webinars and presented by Foresight consultants.

• The tiered program approach will consider participants' experience (Basic Track and Advanced Track).

• Two cohorts, up to 22 participants each.

Training begins February 2024 and June 2024.

- 12 weekly webinars will be followed by one-on-one training with Foresight consultants.
- One-on-One training will be tailored to the needs of specific program participants.
- 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.
- The Final Presentation is a pitch of a mock business plan for the technology within the area of NIAID/NHLBI interests.
- Presentations will include (ideally):
  - Technology Value Proposition
  - Competitive Intelligence Information
  - Market Information
  - IP Information
  - Revenue Model and Revenue Projections
  - Team And Resources Information

## ITEP Program Timeline

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

- NIAID and NHLBI promote the program and the informational webinar via email
- Informational Webinar:
  December 6, 2023
- Foresight develops curriculum and training content

- ITEP Application Period opens: December 8, 2023
- Application link goes live
- Ongoing, first come-first served
- Qualified participants are notified by Foresight

- Webinars begin: February 5, 2024 (Cohort 1)
- 12 live weekly webinars
- Basic Trackinnovators with no business experience
- Advanced Track entrepreneurs seeking additional training
- Cohort 2: Webinars begin June 2024

- One-on-one training begins:
  April 2024
- One-on-one training will solidify participant understanding of curriculum and prepare them for the final presentation
- Final Presentations: May 2024

- 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 December 8.

Please visit
 https://www.cognitoforms.com/foresightsciencetechnolog
 yinc/niaidnhlbiinnovatortoentrepreneurprogramitep

• Enrollment is ongoing until both February 2024 and June 2024 cohorts are filled.

#### Thank You!

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