National Institute of Allergy and Infectious Diseases



SBIR/STTR Grant Programs at NIAID and NIH

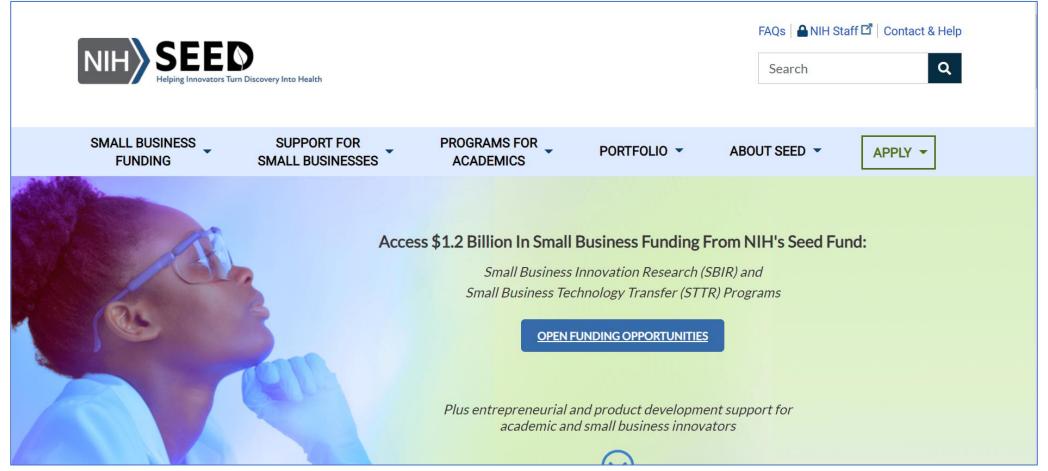
Natalia Kruchinin Ph.D.

NIAID SBIR/STTR Program Coordinator

January 11, 2023

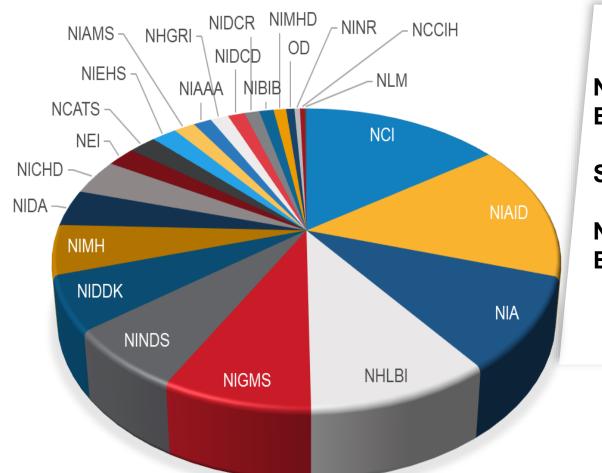


SBIR NIH-Small Business Education and Entrepreneurial Development (SEED)





NIH SBIR/STTR Budget Allocation FY22



NIH SBIR/STTR
Budget > \$1.281Billion

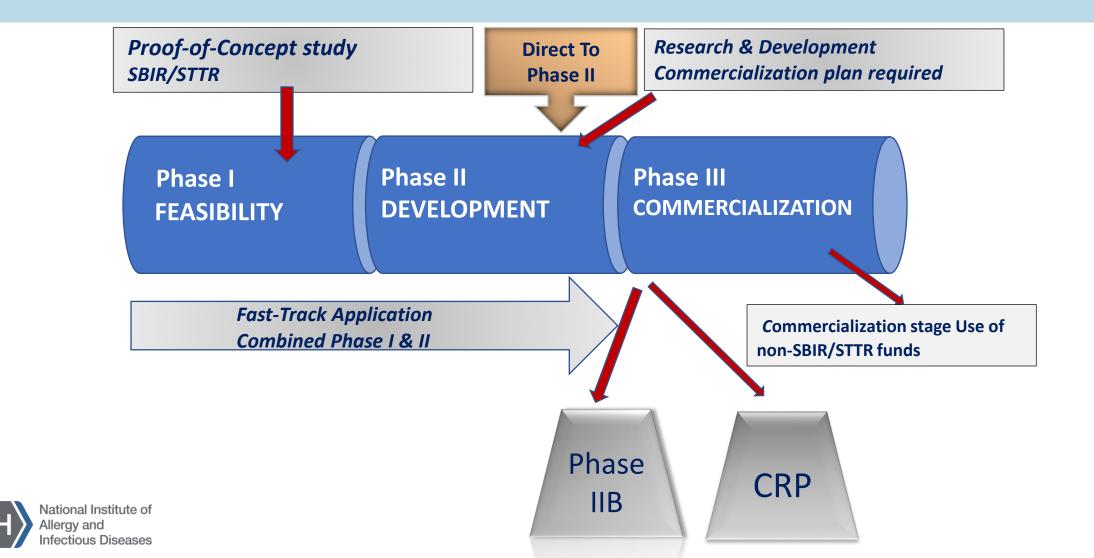
SBIR 3.2% STTR 0.45%

NIAID SBIR/STTR FY21 Budget \$189.9M

SEED NIH



SBIR & STTR: Three-Phase Program



NIH SBIR/STTR Fast-Track

Commercialization Discovery **Development** Competing Renewal Award Phase II Phase III Phase I Phase IIB \$3M for up to 3 years Full R/D Additional R/D **Feasibility** Phase I Phase II Simultaneous submission and review of Phase I and II Fast-Track Phase I is awarded Milestones/aims of Phase I are assessed by program staff Direct to Phase II **BEFORE Phase II is awarded**



Phase Flexibility (Direct-to-Phase II Program)

- Allows small businesses that are ready for the Phase II stage of development to bypass applying for a Phase I grant
- Designed for SBCs that have completed Phase I-type milestones with non-SBIR funds
- Have preliminary data that is equivalent to what we expect from the end of an NIH Phase I award
- Applies to <u>SBIR programs</u> only, NOT STTR and not available for the CDC, FDA, and the Administration for Children & Families (ACF) SBIR programs
- This Application types is included in SBIR Omnibus FOA
- SBIR/STTR Funding





Phase IIB Competing Renewal Award



- SBIR/STTR Phase II awardee (NIAID only SBIR)
- Technologies that require extraordinary time/effort to develop, and often require FDA regulatory approval
- Awards up to \$1M/year for up to 3 years
- No third-party investor requirement

 NIAID
- Contact NIH Program Staff to discuss!



PHS 2022-2 Omnibus Solicitations

- Applications for SBIR/STTR awards are submitted in response to agency solicitations!
- NIH, CDC, & FDA SBIR/STTR Omnibus Grant Solicitations "Parent" FOAs:

NIAID

- Clinical Trial Required: SBIR: PA-22-177; STTR: PA-22-179
- Clinical Trial Not Allowed:

SBIR: PA-22-176; STTR: PA-22-178

Standard Due Dates: January 5th, April 5th, September 5th





NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44 Clinical Trial Required)

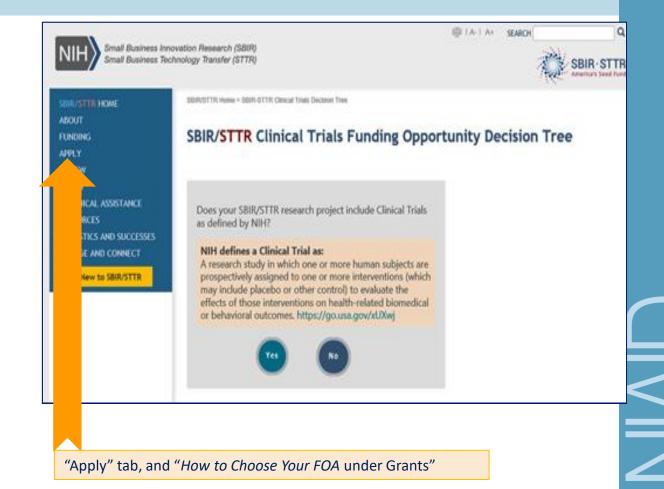
- NIAID does not fund Clinical Trials via standard SBIR/STTR mechanisms, we offer a U44 (Cooperative Agreement) Phase II SBIR Clinical Trial Implementation funding that funds Clinical Trials PAR-21-082
- U44 program supports implementation of clinical trials from small business concerns (SBCs) that propose clinical trials in research areas within mission and goals of the NIAID
- This FOA will accept SBIR Phase II/IIB, Fast-Track and Direct to Phase II applications
- Applicants seeking only SBIR Phase II support must have received SBIR Phase I support that is appropriate and relevant (e.g., pre-clinical studies, planning activities, etc.) to this FOA
- Applies to SBIR programs only
- Questions and Answers for PAR-21-082
- NIAIDU44@mail.nih.gov





SBIR/STTR Clinical Trials Funding Opportunity Decision Tree

- Interactive tool to assist applicants with finding the correct FOA to submit application
- Applicants can answer specific lines of questioning about their project, and each answer will lead them to SBIR, STTR, and clinical trial FOAs, or other helpful, applicable NIH resources.





Commercialization Readiness Pilot (CRP) Program

 Transition of previously or currently funded Phase II and Phase IIB projects to the commercialization stage by providing additional support not typically supported through Phase II/IIB

Commercialization Readiness
Pilot (CRP) Program
Solicitations

The Commercialization Readiness Pilot (CRP) Program has been re-authorized until FY2022.

- SBIR/STTR Commercialization Readiness
 Pilot (CRP) Program Technical Assistance
 and Late Stage Development Clinical Trial
 Not Allowed (PAR-20-129)
- SBIR/STTR Commercialization Readiness
 Pilot (CRP) Program Technical Assistance Clinical Trial Not Allowed (PAR-20-128)
- SBIR/STTR Commercialization Readiness
 Pilot (CRP) Program Technical Assistance
 and Late Stage Development Clinical Trial
 Required (PAR-20-130)

NIAID

PAR-20-129



SBIR/STTR Programs Commercialization Readiness Pilot Program (CRP)

- CRP program can provide up to \$3 million in additional funding for
 - Phase II/Phase IIB SBIR/STTR project
- CRP program may fund work that is not typically supported through SBIR/STTR Phase II or Phase IIB awards, including:
 - Preparation of documents for a Food and Drug Administration (FDA) submission
 - Development of an intellectual property strategy
 - Investigational New Drug (IND)-enabling studies
 - Clinical studies NIAID; no clinical trials
 - Manufacturing costs
 - Manufacturing costs
 - Regulatory assistance
 - Subcontracted work to other institutions, including contract research organizations (CRO)
 - A combination of services



HHS SBIR Contract Solicitation

- FY2023 Contract Solicitation is Closed
- FY2024 Contract Solicitation open date ~end of July 2023
- NIAID 13 SBIR Contract topics
- Please direct all questions to Charles Jackson, NIAID Contracting Officer Phone: (240) 669-5175 Email: charles.jackson@nih.gov
- Program Solicitation PHS 2023-1 (SBIR Only)
- Check SBIR NIH SEED office
- NIH Guide for Grants and Contracts





NIAID FY23 PHS 2023-1 SBIR Contract Topics

FY2023 Contract Solicitation is **Closed**: https://seed.nih.gov/small-business-funding/find-funding/sbir-contracts

Topic #	Title	
113	Development of a Simian Immunodeficiency Virus (SIV) and Simian Human Immunodeficiency Virus (SHIV) Database	
114	Point-of-Care HIV Viral Load, Drug Resistance, and Adherence Assays	
115	Development of Diagnostics to Differentiate HIV Infection from Vaccine-Induced Seropositivity	
116	Adjuvant Discovery for Vaccines for Infectious and Immune-Mediated Diseases	
117	Adjuvant Development for Vaccines for Infectious and Immune-Mediated Diseases	
118	Reagents for Immunologic Analysis of Non-mammalian and Underrepresented Mammalian Models	
119	20 Modular Sample Preparation for In-Field Viral Discovery	
120		
121		
122	Advanced and Immersive Visualization Tools for Infectious and Immune-mediated Disease Research	
123	Data Science Tools for Infectious and Immune-mediated Disease Research	

Please direct all questions to Charles Jackson, NIAID Contracting Officer Phone: (240) 669-5175 Email: charles.jackson@nih.gov





NIAID Organization

Office of the Director (OD)

- 1. <u>Division of AIDS (DAIDS)</u>
- 2. <u>Division of Allergy, Immunology, and Transplantation (DAIT)</u>
- 3. <u>Division of Microbiology and Infectious</u> <u>Diseases (DMID)</u>
- 4. Division of Extramural Activities (DEA
- 1 Division of Clinical Research (DCR)
- 2. <u>Division of Intramural Research (DIR)</u>
- 3. Vaccine Research Center (VRC)

These program Divisions direct and managed the extramural research portfolio. Most of the NIAID budget supports research at academic and research institutions through grants, contracts and cooperative agreements

DEA oversees policy and management activities related to funding grants and contracts and conducts initial peer review for grants and contracts that address NIAID specific needs or focus.

High-Priority Areas of Interest



COVID-19

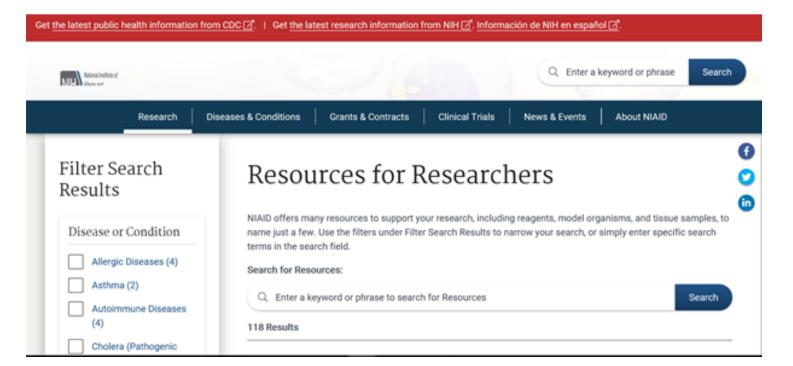
- Most NIH Institutes and Centers made the decision to expire their COVID-19 SBIR/STTR Notices of Special Interest (NOSIs) and direct all on-Mission COVID applications to the SBIR/STTR Omnibuses
- Check: COVID-19 Funding Opportunities & Announcements





NIAID COVID-19 Resources

- NIAID resources has many resources available to the research community to facilitate product development, including an in vitro testing service
- Information about NIAID research resources can be found at: <u>NIAID Resources for Researchers</u>





Biodefense and Emerging Infections Research Resources Repository (BEI)

- The <u>BEI Resources Repository</u> is a central repository that supplies organisms and reagents to the broad community of microbiology and infectious diseases researchers. <u>Materials are available through an online</u> <u>catalog</u>
- There is no charge for research materials (shipping and handling fees may apply)
- Users need not be a grantee of NIAID or another National Institutes of Health Institute or Center
- How To Get Started:
 - Register to place an order
 - Place your order through the online catalog





Award Sizes



- Current SBA Award Funding Amounts adjusted for inflation:
 - Total funding support (direct costs, indirect costs, fee) normally may not exceed \$295,924.00 for Phase I awards and \$1,972,828.00 for Phase II awards
- NIH recognize that some biomedical innovations require additional funding to reach the marketplace. For those topics, the NIH has a waiver from the Small Business Administration (SBA) to allow larger awards. Please refer to a list of <u>SBA approved waiver eligible topics</u>.
- For proposals that address NIAID waiver topics NIAID will allow Phase I applications with budgets
 of up to \$300,000 total costs per year for up to 2 years; and Phase II or Phase IIB applications with budgets of up to \$1,000,000 total costs per year for up to 3 years
- No prior approval is required compliance with a specific topic is confirmed at time of award
- As always, your budget request should be well-justified by the science and consistent with the work proposed



Technical and Business Assistance (TABA)

- Applicants may request additional funding support for technical and business services, such as:
 - Phase I up to \$6,500 per year
 - Phase II cap of \$50,000 for the life of the project
 - In addition to the amount of the award
- Access to technologies, support on product sales, intellectual property protections, market research, and planning, access to technical and business literature available through on-line data bases
- Request within the APPLICATION
- Request in F. Other Direct Costs lines 8-10 on SBC budget Label as "Technical Assistance
- Include a detailed description of the technical or business assistance that your vendor will provide, including the name of the vendor and the expected benefits and results of the technical or business assistance provided in the Budget Justification



Tools to Help Direct Your Application to the Best Place for Review and Funding



Most Important Piece of Advice



- Talk to us before apply!
- Send email to NIAID Program Officer about your application before submission
- NIH Program Officer's contact information found on the <u>HHS Agency</u> <u>Contact webpage</u>
- Dr. Natalia Kruchinin, email: kruchininn@niaid.nih.gov or email NIAIDSBIR@mail.nih.gov
- Please Include non-confidential abstract of your technology/planned specific aims for your future project
- Subscribe to the <u>NIAID SBIR List-Serv</u>





Submit Early!

- There is a 2-day viewing window during which the application can be
 - Rejected
 - Changed
 - Submitted again
- The final version must be in the system before the application deadline
 - If you submit 3 days early, you get 2 days to view the application and fix it.
 - If you submit 2 days early, you get 2 days to view the application and fix it.
 - If you submit 4 hrs early, you get 4 hrs to view the application and fix it.
- Grants.gov will allow you to submit it late (because there are acceptable reasons see NIH Late Application Policy NOT-OD-15-039

But if you submit it late without an acceptable reason it will be caught and withdrawn!



REVIEW IS DONE AT THE NIH'S CENTER FOR SCIENTIFIC REVIEW



Application is submitted to NIH (not the institute)



Please know that even if a NIH institute fit can't be found in advance, you can still apply to the SBIR/STTR <u>Omnibus</u> and allow the Division of Receipt and Referral (DRR) at the Center for Scientific Review (<u>CSR</u>) assign your application to where they feel it would best fit



Get Review Experience - Volunteer yourself as a reviewer https://grants.nih.gov/grants/peer/becoming_peer_reviewer.htm



NIH Application & Review Process



Applicant initiates research idea **Program Staff**



Small Business Concern confirms Eligibility Program Staff/SBA



Submits SBIR/STTR grant application to NIH electronically eRA/Grants.gov Helpdesk



NIH Center for Scientific Review assigns to IC and **IRG** Referral Office

1-2 Months



IC staff prepare funding plan for IC Director **Program Staff Grants** Management



3 Months

Advisory Council or Board recommend Approval



Scientific Review Group evaluates scientific merit

2-4 Months



IC allocates funds

Grantee conducts research





Timeline: New Applications

Award Council Scientific Due Date Date Review Review (earliest) Sept 5 March Oct/Nov Jan/Feb Jan 5 Feb/Mar July May/June April 5 June/July Sept or Dec Aug



Assignment Request Form (ARF) Optional Form

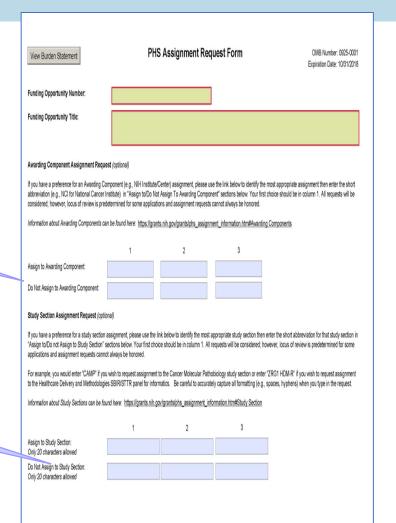
Sample PHS Assignment Request Form

Requests for IC assignment

Requests for SRG assignment

Identify conflicts/Suggest expertise

Do not use a cover letter for this information! National Institute of Illergy and See NOT-OD-16-008



Cover Letters

For Internal use only and will not be shared with peer reviewers

The cover letter can be used to:

- > Explain why the application is late
- ➤ Provide notice of plans to submit a video
- ➤ Identify your project as generating large-scale genomic data

The cover letter cannot be used to:

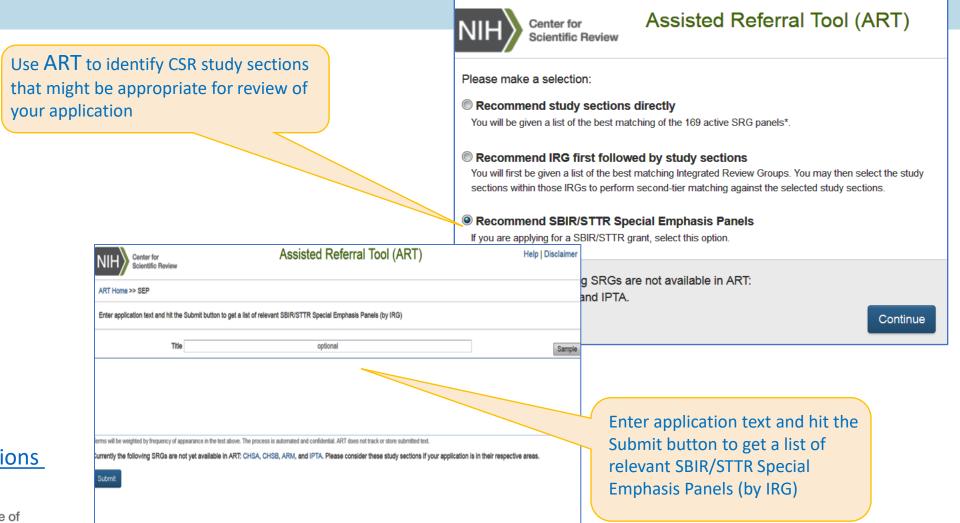
- ➤ Make assignment requests (use the ARF!)
- ➤ Suggest specific reviewers

Read more at NIH Cover Letters





CSR Assisted Referral Tool



List of Study Sections



Important Facts to Remember

- Eligibility is determined at time of award
- PI is not required to have a Ph.D./M.D.
- PI is required to have expertise to oversee project scientifically and technically
- The PI is not required to have US citizenship, but the PI must legally reside in the United States and must be available to perform the research proposed for the duration of the project.
- Applications may be submitted to different agencies for similar work
- Awards may not be accepted from different agencies for duplicative projects
- SBIR/STTR Phase I applications may be submitted to different agencies for SBIR/STTR Phase II
- Grantees may switch between the SBIR and STTR programs



NIAID SBIR/STTR Sample Applications

- SBIR NIH office "Samples of SBIR/STTR applications from NIAID are one of our most NIH requested resources"
- https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44

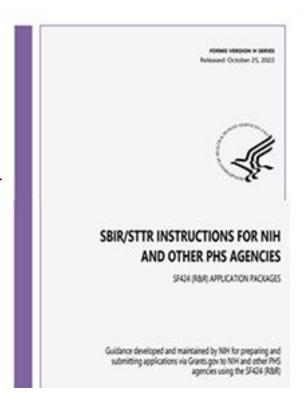
Pl and Grantee Institution	Sample Application
Jose M. Galarza of Technovax, Inc. "Broadly protective (universal) virus-like particle (VLP) based influenza vaccine" (SBIR Phase I/R43)	Full Application
Mark Poritz* of BioFire Diagnostics, LLC. "Rapid, automated, detection of viral and bacterial pathogens causing meningitis" (SBIR Phase I / R43)	Full Application
Patricia Garrett of Immunetics, Inc. "Rapid Test for Recent HIV Infection" (SBIR Phase II / R44)	Full Application
Michael J. Lochhead of MBio Diagnostics, Inc. "Point-of-Care HIV Antigen/Antibody Diagnostic Device" (SBIR Phase II / R44)	Full Application
Kenneth Coleman of Arietis Corporation "Antibiotics for Recalcitrant Infection" (SBIR Fast-Track)	Full Application
Timothy C. Fong of Cellerant Therapeutics, Inc. "Novel indication for myeloid progenitor use: Induction of tolerance" (STTR Phase I/R41)	Full Application
Raymond Houghton, InBios International, and David AuCoin, University of Nevada School of Medicine "Antigen Detection assay for the Diagnosis of Melioidosis" (STTR Phase II/R42)	Full Application



SBIR/STTR: Key Documents



- Omnibus SBIR/STTR Solicitations FY2022
 - SBIR CTR: PA-22-177; SBIR CTN: PA-22-176
 - STTR CTR: PA-22-179; SBIR CTN: PA-22-178
- Use the <u>SF424 (R&R) Version H</u> application form instructions on the <u>How to Apply Application Guide</u> page.
- NIH Grant Policy Statement
- Annotated Form Set Forms G
- SBIR/STTR On-Line Tutorials
- "FORMS-H" (NOT-OD-22-195)





NIAID Applicant Assistance Program (AAP)

- Designed to provide small businesses with professional guidance that will help them with crafting a strong Phase II Small Business Innovative Research (SBIR) or Small Business Technology Transfer (STTR) application
- Provides no cost support for NIAID applicants planning to apply for a Phase I, Phase II/IIB, Fast Track, or Direct-to-Phase II SBIR/STTR Award.
- Applicant preparation support, proposal development training, customized one on one applicant assessment and post submission support
- First 35 eligible applicants applied for each cycle will be enrolled in the program.

AAP information webinar ~ one week before enrollment day

Subscribe to the NIAID SBIR List-Serv



- FY22 Cycle 3
 - o Enrollment 1/3/2023-1/17/2023,
 - AAP assistance period 1/17/2023-3/29/2023
- FY23 Cycle 1
 - o Enrollment Mid-May, 2023-June, 2023
 - AAP assistance period June, 2023-August, 2023
- FY23 Cycle 2
 - o Enrollment Mid-September, 2023-October, 2023
 - o AAP assistance period October, 2023-December, 2023
- FY23 Cycle 3
 - o Enrollment Mid-December, 2023-January, 2024
 - AAP assistance period January, 2024-March, 2024

NIAID Applicant Assistance Program (AAP) Eligibility Criteria: Expanded to Accommodate Phase I Applicants

- The research area of interest aligns with the mission of NIAID. Read <u>NIAID</u>
 <u>High-Priority Areas of Interest</u> to help you determine if your application aligns with the mission of NIAID
- The company intends to submit a Phase I, Phase II/IIB, Fast Track, or Direct-to-Phase II SBIR/STTR application (Completion of the <u>4 required registrations</u> is strongly recommended for all applicants)
- Phase II applicants must be within the <u>first six receipt dates</u> following the expiration of the Phase I budget period
- The company must be eligible to apply for NIH SBIR/STTR grants based on the NIH Small Business Eligibility Criteria.
- Subscribe to the NIAID SBIR List-Serv





Tools to Help Direct Your Application to the Best Place for Review and Funding

- Use <u>NIH RePorter</u> to locate funded applications in your field and discover:
- The NIH Institutes and Centers that fund this field of research
- The program officers who can guide you before submission and after the results of the review
- You can use the Matchmaker function or a text search
- The scientific review groups (located in Project Information) in which they were reviewed





Government Spending by Agency





Links below can be useful when putting together your SBIR/STTR application

- NIH SEED Office
- Registrations prior to NIH application submission (SAM.gov registration process is experiencing delays so you should allow extra time for this step, if needed. They are estimating that there's at least a 10-day registration turnaround time!)
- PHS 2022-2 Omnibus Solicitations
- SBA-Approved Topics for Budget Waivers. Annotated Form Set for NIH SBIR Grant Applications NIH Grants Policy Statement
- "How to Apply"
- instructional videos, presentations
- infographic
- NIAID SBIR/STTR Grant Applications
- NIA Sample SBIR Grant Applications
- NCI Sample SBIR/STTR Grant Applications
- SBIR/STTR Study Sections
- Assignment Request Form (Form to indicate your preference for which institute you would like to fund your application)
- CSR Assisted Referral Tool (May be used to identify appropriate study sections for your application)
- RePorter NIH
- <u>NIH Matchmaker</u> (May be used to identify similar funded projects and Program Officers)



NIAID Small Business Program Team



Natalia Kruchinin, Ph.D. (<u>kruchininn@niaid.nih.gov</u>)
NIAID SBIR/STTR Program Coordinator







Patricia Roth, MS <u>patricia.roth@nih.gov</u> Small Business Development Specialist





Small Business Development Specialist
TBD



THANK YOU!





NIH Peer Review

- A Scientific Review Officer (SRO) in CSR manages the initial peer review.
- The study section meets and assesses their assigned applications against the review criteria stated in the funding opportunity.
- An impact score and summary statement is provided for each peer reviewed application.
 - •Impact score reflects your reviewers' judgment of the extent to which your project can make an impact. NIH defines impact as the likelihood that your project will exert a powerful influence on its field.
 - Impact scores may be numeric (10 90) or alphabetical (ND for Not Discussed)
 - Available in eRA Commons 2-3 days after review
- Summary Statement combination of the reviewers' written comments and the SRO's summary
 of the members' discussion
 - Available in eRA Commons within a month of review

National Institute of Allergy and Infectious Diseases

- NIH Peer Review
- <u>List of CSR study sections</u>
- SBIR/STTR Study Section

NIH supports SBIR/STTR biomedical research through grants, contracts, and cooperative agreements

		No substantial involvement is
Grant	entity to carry out an approved project or	anticipated between government and recipient during the performance of activity
Contract	a non-tederal party services for the direct	Involvement is usually substantial
Cooperative Agreement	programmatic involvement. Substantial involvement means that, after award,	Substantial amounts anticipated between government and recipient during performance of activity.

Grant mechanism ~90%

NIH SBIR/STTR awards

Contract mechanism ~10%



