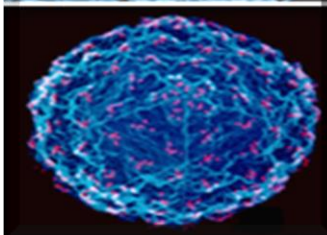
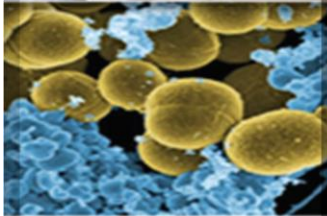




National Institute of Allergy and Infectious Diseases (NIAID), NIH

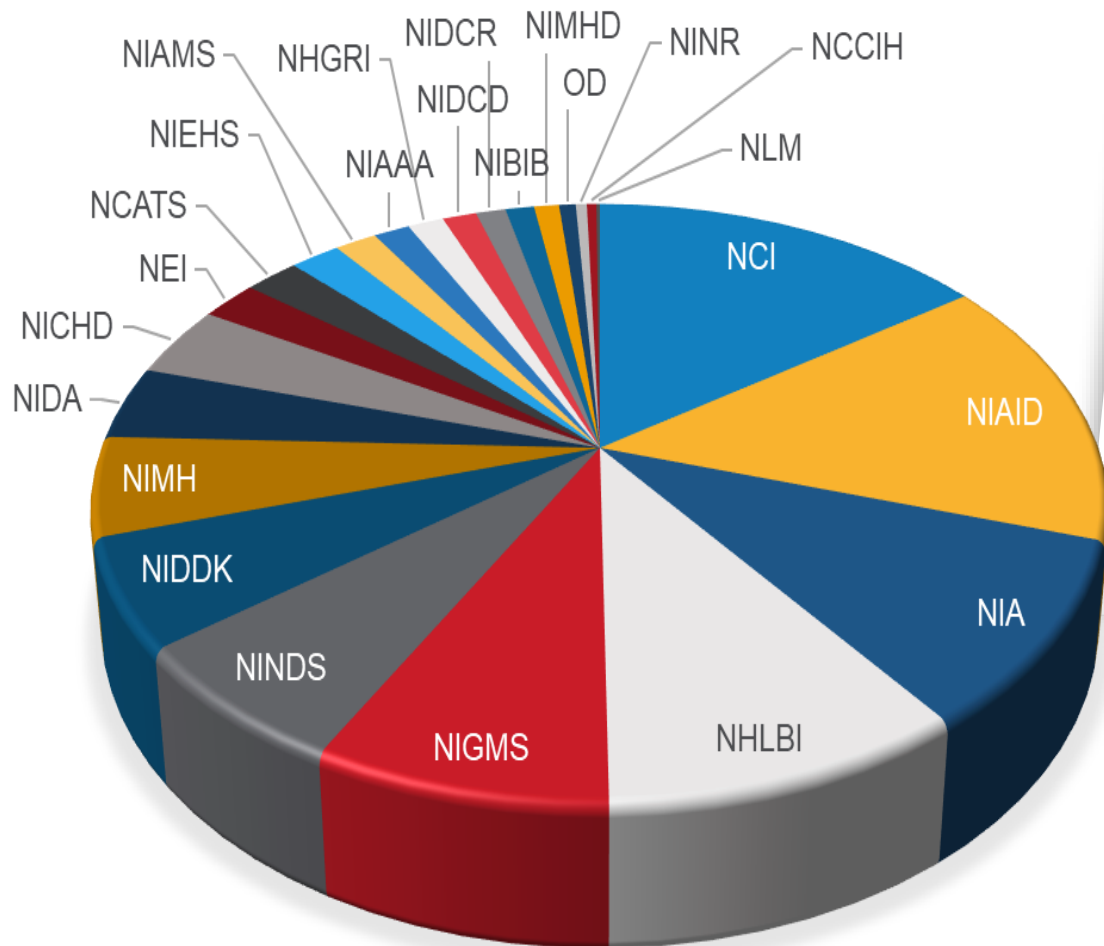


Applicant Assistance Program (AAP) NIAID SBIR/STTR Program Information Webinar

Hejiao English, Ph.D.
Small Business Development Specialist
Small Business Program, NIAID, NIH

August 27, 2024

NIH SBIR/STTR Budget Allocation FY24



**NIH SBIR/STTR Budget
\$1.264 billion (B)**

**NIAID SBIR/STTR Budget
\$193.8 (M)**

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).

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.

Technical and Business Assistance (TABA)

- Applicants may request additional funding support for technical and business services:
 - 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
- Qualifying services include but not limited to assistance with product sales, intellectual property protections, market research and/or validation, development of regulatory plans, development of manufacturing plans, and access to technical and business literature available through online databases.
- Request this funding within the **application** in section F. Other Direct Costs, lines 8–10 on the Small Business Concern (SBC) budget; label the funding 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.



- **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 [HHS Agency Contact webpage](#).
 - NIAID: **Dr. Natalia Kruchinin** (NIAID Small Business Program Coordinator), kruchininn@niaid.nih.gov
- or
- NIAID SBIR/STTR: NIAIDSBIR@mail.nih.gov
- Please include a non-confidential abstract of your technology and planned specific aims for your future project.
- **SUBMIT EARLY (days, not hours and minutes)!**

NIAID Applicant Assistance Program (AAP) Eligibility Criteria

- The company must be eligible to apply for NIH SBIR/STTR grants based on the **NIH Small Business Eligibility Criteria**.
- The research area of interest aligns with the mission of NIAID. Read **NIAID High-Priority Areas of Interest** 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 (including U44)** SBIR/STTR application. (Completion of the **four required registrations** is strongly recommended for all applicants.) **CRP and Contract** applications are **not eligible** to participate.
- The company intends to submit an application for the **January 5, 2025**, SBIR/STTR grant submission deadline.
- Phase II applicants must be within the **first six receipt dates** following the expiration of the Phase I budget period.

NIAID AAP Application Form Link and Office Hour

- The NIAID AAP will be open for applications on **September 9, 2024, at 12:00 p.m. EDT**. **Submit your application** via the link below as soon as the form opens:

<https://www.cognitofrms.com/ForesightScienceTechnologyInc/NIAIDApplicantAssistanceProgram>

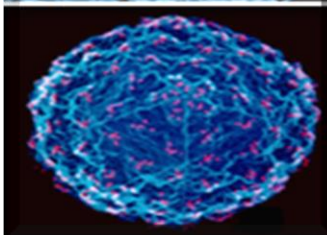
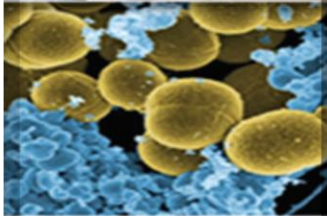
- The NIAID AAP is hosting an **Office Hour** session on **September 11, 2024, from 2-3pm EDT**. During the office hour, NIAID Small Business Program staff and representatives from our supporting contractor company Foresight Science & Technology will be available to answer any questions applicants might have regarding the AAP including eligibility criteria, application process, available resources, how to work effectively with AAP consultants.

Register at: <https://events.gcc.teams.microsoft.com/event/c815c6e8-d263-492f-b560-844853d989c1@14b77578-9773-42d5-8507-251ca2dc2b06>

- For all future NIAID program announcements, please subscribe to the **NIAID Small Business List-serv**: <https://service.govdelivery.com/accounts/USNIAID/subscriber/new>.



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



Thank you!

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NIAID Small Business Program Applicant Assistance Program (AAP) Information Webinar

Konstantin Izvolsky, Ph.D.

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

August 27, 2024



NIAID AAP Overview

- The NIAID Small Business Program established an AAP providing SBIR/STTR applicants no-cost training and advising services to increase success for SBIR/STTR applicants.
- This program is intended for eligible **NIAID Phase I, Phase II/IIB, Fast-Track, and Direct-to-Phase II applicants.**
- This program has an emphasis on engaging and assisting groups underrepresented in extramural biomedical small business programs.



Foresight Science & Technology: Your AAP Service Provider

- Small-business consulting company headquartered in Massachusetts
- World-leading full-service provider of technology transfer, commercialization, due diligence, and intellectual property management services for clients including government agencies, companies, laboratories, foundations, universities, and investors
- Subject matter expertise: 60 Senior Consultants with expertise across all industries



Foresight Services for SBIR/STTR Applicants & Awardees

- Grant proposal review and fine-tuning
- Business plan review and fine-tuning
- Developing the commercialization strategy
- Identifying funding sources
- Identifying partners for technology testing, validation, and prototyping
- Obtaining a letter of support
- Outreach to key opinion leaders and end-users
- Custom Technical and Business Assistance (TABAs) services depending upon the company's specific needs and objectives



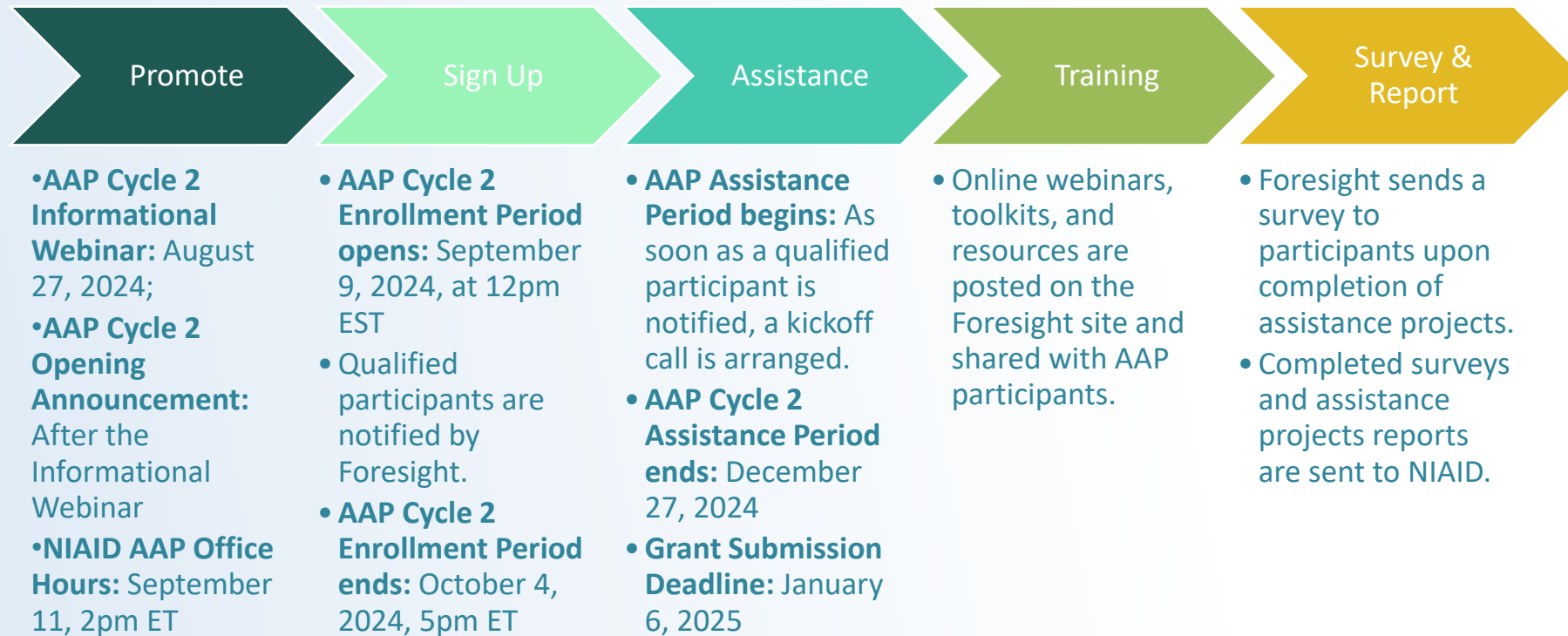
Foresight Science & Technology: Long History of Supporting NIH SBIR Programs

- More than 15 years of providing commercialization support to NIH SBIR/STTR awardees:
 - NIH-wide SBIR Phase I Commercialization Assistance (Niche Assessment Program)
 - SBIR/STTR program support for the National Institute of Mental Health
 - Technology transfer support program for the Centers for Disease Control and Prevention
- In-depth understanding of the needs of SBIR/STTR awardees related to preparation of technical/scientific sections of their proposals and drafting compelling commercialization plans necessary to bring the new technologies to market
- We know how to create compelling SBIR/STTR Phase II, Direct-to-Phase II, and Fast-Track proposals, and how to successfully present them to reviewers.

NIAID AAP Structure

- The AAP program has three cycles for the following SBIR/STTR application submission deadlines:
 - September 5, 2024
 - **January 6, 2025**
 - April 7, 2025
- The first 35 eligible applicants for each cycle are enrolled in the program.

NIAID SBIR/STTR AAP Cycle 2 Workflow and Key Dates





NIAID SBIR/STTR AAP: Support

- One-on-One Proposal Preparation Assistance
 - Provided by Foresight Science & Technology, Inc.
 - Virtual consulting and advising on all aspects of SBIR Phase I, Phase II/IIB, Fast-Track, and Direct-to-Phase II grant preparation and submission
- Online Training Resources
 - Training webinars
 - Toolkit of guidelines, templates, and samples



One-on-One Proposal Preparation Assistance

- Assistance Overview

- Foresight Science & Technology Senior Consultant assigned to each AAP participant
- Kickoff call with AAP participant: This call will provide initial company assessment (resources, needs, deficiencies); NDA execution (if necessary)
- Customized Assistance Plan development
- Customized Assistance Plan implementation



One-on-One Proposal Preparation Assistance

- Customized Assistance Plan Development
 - Initial application assessment, strategic planning, applicant resources, NIH-specific guidance, resubmission guidance
 - A timeline for review of each element of proposal requested by AAP participant, including bio-sketches, budget, research strategy, commercialization plan, and supplementary forms and documents
 - Specifically for Phase I: NIAID resources, topic identification, budget basics, and registration guide
- Customized Assistance Plan Implementation
 - Will offer proposal editing, advising, and reviewing (**NOT WRITING**) of project content for consistency on each component of the proposal requested by the AAP participant
- Feedback will be provided via iterative reviews with corrections and notes for improvement.



Online Training Resources

- These resources include pre-recorded webinars and a toolkit addressing the key component of the SBIR grant application package and the grant submission, resubmission, and management process.
- Webinars
 - Program Basics
 - SBIR/STTR Program Overview
 - Resources available through NIAID and NIH SBIR/STTR
 - Before You Begin: Planning Your Project and Proposal
 - Navigating Required Registrations
 - Phase I planning
 - Phase II Planning
 - Update to the SF424 Application Package (Version H) and the new Data Sharing Plan



Online Training Resources

- Webinars:
- Budgets
 - Phase I Budget
 - Phase II Budget
- Research Plan
 - Phase I Research Timeline and Outcomes
 - Phase II Research Timeline and Outcomes
- Creating A Compelling Commercialization Plan
- Supplementary Documents and Forms
- ASSIST Tutorial

Online Training Resources

- Webinars:
 - Common Pitfalls, Proposal Review and Resubmission
 - Common Weaknesses in Applications and Pitfalls in the Process
 - Understanding the Review Process and Scoring
 - General Resubmission Process
 - Strategic Approach to Resubmission/ Responding to Reviewers
 - Post-Award Grant Management

Online Training Resources



Toolkit Item	Description
Registration Review	Required registrations, sheet for tracking passwords, what to check and when
SBIR/STTR Proposal Checklist (Phase I and II)	Listing of all required sections for a successful SBIR/STTR submission (to ensure no required document is left out of the application package)
Budget Justification Template (Phase I and II)	A template that provides a clear description of what goes under each budget category and the level of detail recommended
Data Management and Sharing Template	NIH requires all applicants planning to generate scientific data to prepare a DMS Plan that describes how the scientific data will be managed and shared.
Excel Template for Budget Planning (Phase I and II)	The template can be used to calculate budget and check distribution of percentages depending on SBIR or STTR (to ensure compliance with guidelines)
Subaward Documents Required/Information Needed Checklist	Review of the process of requesting subaward documents, information that research institutions require, timelines usually required (when to request, when to ask to have them back, etc.)
Specific Aims and Research Plan Template (Phase I and II)	This is an annotated version of the NIH SBIR/STTR Research Plan guidelines.
Phase II Commercialization Plan Template	This is an annotated version of the NIH Phase II Commercialization Plan guidelines.
Letters of Support/Bio-Sketch Templates	Different letter of support templates that include a description of required information for a letter to be “meaningful” in the application
Human Subjects/Clinical Non-Clinical Trial Checklist	If human subjects are involved, certain documents are required. If clinical trials are proposed, there are additional documents required. This checklist will prepare applicants for required documents for both.
ASSIST Cheat Sheet	Quick overview of some common areas of error on the forms and what to select on some tricky questions (new proposal, renewal, etc.)

Before Applying for the AAP

By the time of AAP application, the participant is strongly encouraged to—

- Ensure that the research area of interest aligns with the mission of NIAID
- Have preliminary discussions about the feasibility of Fast-Track and Direct-to-Phase II approaches with the NIAID Program Officer (in the absence of a Phase I SBIR award)
- Initiate (as a minimum) the company registration process
- Assess available resources and background research (particularly, if currently not in Phase I)

Success of AAP

Critical factors for the success of AAP participants include—

- Communication with the Foresight Senior Consultant
- Sticking to the customized Assistance Plan
- Being proactive
- Committing to the submission deadline



Thank You!

Contact:

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Director of Consulting & Training

1-401-273-4844 ext. 4003

konstantin.izvolsky@foresightst.com