From Lab to Market: Funding and Commercialization Resources for Early-stage Start-ups from The National Cancer Institute

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Small Business Innovation Research (SBIR) Development Center National Cancer Institute (NCI)



TODAY'S SPEAKERS



Jonathan Franca-Koh, PhD, MBA Team Leader & Program Director SBIR Development Center National Cancer Institute



Monique Pond, PhD Team Leader & Program Director SBIR Development Center National Cancer Institute

OUTLINE OF THE TALK

- Overview SBIR/STTR Program
- Funding Opportunities
- Commercialization Resources and Assistance for Applicants
- Application Tips and How Program Directors Can Help
- Q&A

OVERVIEW SBIR/STTR PROGRAM

CONGRESSIONALLY MANDATED PROGRAM

		Jet Aside IOI 1125
SBIR SMALL BUSINESS INNOVATION RESEARCH	Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization Federal agencies with an extramural R&D budget > \$100M	\$178M (3.2%)
STTR SMALL BUSINESS TECHNOLOGY TRANSFER	Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization <i>Federal agencies with an extramural R&D budget > \$1B</i>	\$25M (0.45%)
	Total	\$203M for NCI \$1.3B for NIH

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SBIR AND STTR PARTICIPATING AGENCIES

11 Federal Agencies





27 INSTITUTES & CENTERS AT THE NIH



WHY SEEK SBIR FUNDING?





Provides seed funding for innovative technology development //

Not a Loan

No repayment is required Doesn't impact stock or shares in any way (i.e., non-dilutive). IP rights retained by the small business //

NIH does not request intellectual property for the SBIR- or STTR-funded technologies. Provides recognition, verification, and visibility //

Every application is rigorously assessed by NIH Peer Review system.



Helps attract additional funding or support //

In addition to funding, we provide commercialization resources to help advance your project.

Т

ELIGIBILITY

Applicant must be a Small Business Concern (SBC)

Organized for-profit U.S. business (based in the U.S. and work performed in the U.S.)

500 or fewer employees, including affiliates > 50% U.S.- owned by individuals and independently operated

OR

> 50% owned & controlled by another (one) business concern that is > 50% owned & controlled by one or more individuals

OR

> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these (SBIR ONLY)

The award is ALWAYS made to the small business concern





SBIR/STTR FUNDING PHASES



SBIR VERSUS STTR

SBIR		STTR		
<u>Permits</u> research institution partners (e.g., universities)	PARTNERSHIP	Requires research institution partners (e.g., universities)		
Small business may outsource ~33% of Phase I activities and 50% of Phase II activities DIVISION OF LABOR		Minimum 40% of the work should be conducted by the small business (for profit), and minimum of 30% by a U.S. research institution (non-profit)		
The PD/PI's primary employment (i.e., >50%) MUST be with the SBC for the duration of the project period	PI INVOLVMENT	PI primary employment not stipulated (min.10% effort to project)		

The award is ALWAYS made to the small business concern.

NCI SBIR DEVELOPMENT CENTER & FUNDING OPPORTUNITIES

PORTFOLIO

• 475+ active projects • \$192M SBIR/STTR funds in FY 2022 (81% grants, 19% contracts)



PATIENT IMPACT (2020-2023)



Mergers, Acquisitions, and Venture Financing

¢112 00D		M&A Deal Value (\$M)	Venture Financing Deal Value (\$M)
in M&A deals	2020	28,862.00	846.70
	2021	9,628.10	932.12
	2022	7,696.80	1,079.27
\$3.5B	2023	57,693.36	657.79
in venture financing	Total	113,880.26	3,515.88

FUNDING MECHANISMS



GRANTS VERSUS CONTRACTS

GRANTS

Investigator-defined within the mission of NIH

NIH Center for Scientific Review (CSR)

May speak with any Program Officer

3 times/year for Omnibus

NO

Based on score during peer review

One final report (Phase I); Annual reports (Phase II)

Scope of the proposal	Defined by the NIH (focused)		
Peer Review Locus	NCI DEA (target 50% business reviewers)		
Questions	MUST contact the contracting officer		
Receipt Dates	Only ONCE per year		
Set-aside of funds for particular areas?	YES		
Basis for Award	If proposal scores well during peer review, must then negotiate to finalize deliverables with NIH		
Reporting	Kick-off presentation, quarterly progress & final reports		

CONTRACTS

FUNDING OPPORTUNITIES

TITLE	SBIR NOFO	STTR NOFO	RECEIPT DATES	
Omnibus Solicitation	PA-23-230 (General) PA-23-231 (Clinical trial required)	PA-23-232 (General) PA-23-233 (Clinical trial required)		
NOSI: Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings	NOT-CA-21-062	NOT-CA-21-062	Standard due dates (January 5; April 5; September 5)	
NOSI: SBIR Technology Transfer	NOT-NS-22-017	N/A		
NOSI: Utilization of Cohorts and Prospective Study Designs for Liquid Biopsy Assay Validation for Early Detection of Cancers	NOT-CA-23-004	NOT-CA-23-004		
NOSI: RNA Delivery Technologies to Allow Specific Tissue Target Homing (RNA-DASH)	NOT-AI-24-007	NOT-AI-24-007		
Small Business Transition Grant for Early Career Scientists	N/A	RFA-CA-23-035	Closed	
NCI SBIR Phase IIB Bridge Award	RFA-CA-23-034		Closed	
NCI SBIR Concept Award (Contract)	75N91023R00034		Closed	
Contract Solicitation	PHS 2024-1		Closed	

INNOVATIVE CONCEPT AWARD



Solicitation: 75N91024R00013

Deadlines:

- White Paper: June 5, 2024
- **Full Proposals:** September 23, 2024

Informational Webinar Registration Links: May 9, 2024 at 2:00 p.m. ET May 23, 2024 at 2:00 p.m. ET

Goal

- Support early stage high-risk/high-reward technologies in pediatric/rare cancers
- De-risk disruptive innovation
- \$300K Contract 1-year projects

Special Features

- Preliminary data are not required
- Submission of White Paper to get Program input
- Short proposals (25 pages v/s 50) fillable template
- Special review criteria (50 % scoring is based on innovation)
- Make awards rapidly (within six months)

Support

- Leverage NIH I-Corps Program
- Transition to Phase II awards for top performers
 - Phase II \$3M
 - Fast-track \$3.5M

SMALL BUSINESS TRANSITION GRANT

Funding support for early-career academic entrepreneurs (e.g., Postdocs) to advance innovative technologies from the academic lab bench to the clinic.



- First of its kind of funding opportunity at the NIH and the NCI.
- \$2.4M Fast-track award for early-career entrepreneurs that combines a Phase I STTR & Phase II SBIR. (Maximum 10-years from terminal degree)
- Mentoring team is key component of the award critical for successful transition to product development.
- Created to directly address gap reported by academic entrepreneurs at NCI-designated Cancer Centers.
- Solicitation (2023): <u>RFA-CA-23-035</u>
- Application deadline: ~August 2024
- Anticipated release date for a new solicitation: April 2024
- Interested companies to send letter of intent 30 days prior to deadline

SMALL BUSINESS TRANSITION GRANT



NCI SBIR PHASE IIB BRIDGE AWARD



- Solicitation: <u>RFA-CA-21-036</u> (Closed)
- Funding: \$4.5 Million over the period of 2-3 years
- Eligibility: Phase II awardees from any Federal agency with cancer-focused projects
- Matching funding:
 - Awardees leverage federal funding to attract private investments and partnership with strategic partners
 - Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., ≥ 1:1 match)
- Through FY 2021, Phase IIB Bridge program has made
 - 2-6 awards/year (46 awards in total)
 - **\$121 Million** in funding distributed
 - Companies leveraged NCI SBIR funding to secure \$4 from third party for every \$1 from NCI SBIR (2017 data)
 - 16 products launched including new devices, diagnostics, and research tools for cancer patients

NCI SBIR PROGRAM COMMERCIALIZATION RESOURCES

NCI SBIR ASSISTANCE: NON-FUNDING RESOURCES



PEER LEARNING AND NETWORKING WEBINARS

Part I. Presentation

Watch pre-recorded panelist presentation on the PLAN webpage prior to joining the webinar and write down your questions.



Part II. Panel Session

Attend real-time panel session and ask your questions to the panelists and/or the moderating NCI SBIR program director.

Video Content Available Online:

- First Steps for Starting a Small Business (4 speakers)
- Implementing a Quality Management System (QMS) (6 speakers)
- How to Write a Good Specific Aims Page (4 speakers)
- Keys to a Successful IND Submission (4 speakers)

PEER LEARNING & NETWORKING (PLAN)

<u>Next Webinar:</u> How To Write A Strong Commercialization Plan

June 13, 2024 Registration Link

Content To Be Covered:

- Commercialization Plan Resources
- Market, Customer, and Competition
- Intellectual Property Protection
- Finance Plan
- Production and Marketing Plan
- Revenue Stream
- Regulatory Pathway
- Reimbursement Considerations



Sid Selvaraj Arima Genomics CEO



Manijeh Goldberg Privo Technologies CEO



Beatrice Langton-webster Cancer Targeted Technology CEO



Madelyn Trupkin Herzfeld Carevive Systems Founder & Vice Chairman



Carlos Castro-Gonzalez Leuko Cofounder & CEO

NIH ENTREPRENEURSHIP BOOTCAMP

Notice: NOT-OD-24-103

- Designed to equip life science investigators and nascent companies with entrepreneurship training
- <u>Target audience</u>: innovators that have not yet been awarded an SBIR/STTR; don't need to have company
- Teaches participants to develop stronger business models, market strategies, and commercialization plans in advance of their initial SBIR/STTR application.
- 2 person teams consisting of a technical lead and business lead
- 8-week program
- First due date for applications: May 13

I-CORPS AT NIH



Funding Opportunity Announcement (FOA) PAR-22-073

- Intensive Entrepreneurial Immersion course aimed at providing teams with skills and strategies to reduce commercialization risk
- Curriculum emphasizes *Reaching out to Customers* to test hypotheses about the market(s) for the technology
- Teams are expected to conduct over *100 interviews* in 8 weeks
- Format is focused on *Experiential Learning*
- NCI SBIR designed, launched, and manages the program for NIH
- 24 Institutes at NIH and CDC participate

https://sbir.cancer.gov/icorps

NIH APPLICANT ASSISTANCE PROGRAM (AAP)

FREE 10-week program that provides a mentor for applicants, who have never applied/won an SBIR/STTR award, to prepare and submit a Phase I SBIR/STTR application



One-on-one, weekly mentoring for application preparation support

-	
-	
-	

Review of every application component (i.e., specific aims page, budget, etc.)



Guidance on registration and submission process



Omnibus deadlines Next application opens April 25, 2024



Especially encourage businesses that are:

- Owned/run by women
 - Owned/run by racial/ethnic groups underrepresented in biomedical research
 - Owned/run by individuals from socially and economically disadvantaged backgrounds
 - Located in NIH IDeA states

NIH APPLICANT ASSISTANCE PROGRAM (AAP)

COVERED TOPICS INCLUDE:

- Registrations
- Specific Aims Page
- One-on-one meeting with NIH SBIR Program Director
- Research Strategy
- Budget
- Biographical Sketches
- □ Letters of Support
- □ Submission Platform Navigation



TIPS ON GETTING STARTED & WRITING A STRONG SBIR/STTR PROPOSAL

GETTING STARTED



Read the solicitation & SF424 carefully to understand the requirements.

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/sbir-sttr-forms-g.pdf



Review similar, currently-funded NIH SBIR/STTR projects. *https://projectreporter.nih.gov/reporter.cfm*



Look at some sample applications.

https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44

https://sbir.cancer.gov/resources/forapplicants#Sample



Check out our Peer Learning And Networking (PLAN) Videos. <u>How to Write a Good Specific Aims Page</u>

First Steps for Starting a Small Business

FORMS VERSION H SERIES Released: August 5th, 2023



SBIR/STTR INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES

SF424 (R&R) APPLICATION PACKAGES

HELPFUL TOOLS: NIH PROJECT REPORTER







Quick Tutorial

TIP #1: REFINE YOUR PRODUCT VISION

- Start informal discussions to clarify the product vision
 - Technical experts, potential customers, investors, commercialization partners, and other stakeholders
- Determine the scope of your project and identify the appropriate funding opportunity
 - Reach out to SBIR program staff to discuss whether your project is a good fit



PRODUCT FOCUSED SCIENCE



PHASE I PROOF OF CONCEPT EXAMPLES



DIAGNOSTICS

- Prelim data: biomarker selection, small cohort
- Proposed studies:
 - Analytical validation (sensitivity and specificity)
 - Preliminary efficacy using human subject samples
- Phase I critical milestone: efficacy (clinical evaluation)

R INTERVENTIONAL DEVICES & DIAGNOSTICS

- Prelim data: lab prototype, initial engineering
- Proposed studies:
 - Develop a working prototype
 - Feasibility in animal models or phantoms
- Phase I critical milestone: efficacy studies

II

HEALTH IT

- Prelim data: initial algorithm development, surveys with potential users
- Proposed studies:
 - Develop a working prototype
 - Reimbursement model development
 - Usability and acceptability testing
- Phase I critical milestone: usability and early efficacy

TIP #2. START EARLY

Strong proposals take time to develop

- Refine your product
- Gain access to equipment, facilities, other resources
- Assemble a strong scientific team
- Obtain letters of support collaborators (and others!)
- Complete required registrations

Resources for New Applicants:

https://sbir.cancer.gov/resources/forapplicants

REQUIRED REGISTRATIONS FOR NIH GRANTS

- System for Award Management (SAM) Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration.
- <u>Grants.gov</u> Grants.gov is a federal-wide portal to find and apply for federal grant funding. It is used by all 26 federal grant-making agencies.
- **3.**<u>eRA Commons</u> eRA Commons is NIH's Electronic Research Administration system that allows applicants, grantees, and NIH staff to access, share and transmit application/grant information.
- **4.** <u>SBA Company Registry</u> All applicants are required to register at the SBA Company Registry prior to application submission and attach proof of registration to their application.

TIP #3. REMEMBER THE REVIEW CRITERIA



*Not a score driving criteria alone, but commercialization potential is evaluated as part of significance

TIP #4. KNOW THE APPLICATION COMPONENTS



SPECIFIC AIMS PAGE ADVIC

The Alms Page

The specific aims gaps is a critical page to an SIBU/STTR application. The aims page should be treated as a translation page to mixelial a review com gain a reasonable understanding the projects official components without making any other parts of the application. Applicants are only allowed one page for their specific status. Application are assigned 15 as 04 primary molecular who are responsible for this is config and acting an primary discussants during the larger pare molecular panel. Others the primary molecular during an and the page relative panel to read the application is in methyler. For applications that are discussed, the final primary score will be set <u>after</u> discussion by a panel of 20 pare releases. Many of the pare molecular will likely only application school be well-cale of an eff be roughly thousand applications meabers by NGI SBB the program smanule.

The first half to two-thirds of the aims page should cover key background information. The background should clearly convey three things;

 The product. A clear product description is critical to as SBIR application and is often a key difference separating an SBR application from a basic science or discovery colonics application. SBIR grants are intended printing for product development, whereas basic/discovery grants are primarily intended for the advancement of knowledge.

The Significance. A problem/proposed solution format often works well to convey significance. If there is an unmet clinical need, it will help the application for this need to be clearly stated.

3. The innovation. How will the product change the current pandigm or practice? How will those affected by cancer benefit from this product being commercially available? The atms page should convey this information as well as provide some standa highlights of the preliminary data as supporting evidence that the product will perform as proposed.

The second half is constructed with a sine raise through disk incur exactly almost variant ways and model proposed to complete such almost half and care holded and the training the model. A followed by lay ansays and model proposed to complete such almost the second structure and the model of the second structure of the second structure control ways and the second structure and the second structure and the second structure control ways and the second structure and the second structure creates. When we reasonable, the second creates a hold to define all optications and provide creates when early qualitative success of their a hold to be defined by qualitative metricity. The second structure and the second structure and the second structure and the second structure applications, a spling a dividition at the and of the place to component should be behaver.

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Overall, an SBR application should focus on the product. Each section of the application should focus on how the proposed work will improve product commercialization. Successful SBR/STIR applications clearly describe how the product will benefit a population affected by cancer, and identify the customer.

IMPORTANT: This guide page in meant to be used as advice for applicants and is not intended as program requirements. This advice page was developed based only on the opinions of several NIH SBIR Program Directors and successful SBIR awardnes.

BACKGROUND:

Product Innovation Significance

AIMS:

Goals-based statements Key assays and models <u>Quantitative</u> milestones

CONTEXT:

These studies will get us to... Next we will...

This data will be used for...



Check out our Peer Learning And Networking (PLAN) videos How to Write a Good Specific Aims Page

BUDGET CONSIDERATIONS

TOTAL COST BUDGET (DIRECT + INDIRECT + PROFIT FEE)

Total Costs

- SBIR budgets are defined by total cost, and subcontracting is limited. Know the rules and the criteria.
- Check the budget allowance for each funding opportunity.

Check IC Limits

- Budgets vary by IC
- Waiver for technology-specific areas
- NCI- Phase I-\$400,000; Phase II-\$ 2.25 million

Fee

- Can request a 7% fee: Company profit
- Part of the total budget

Technical Assistance Money (TABA)

- Phase I- \$6,500
- Phase II- \$50,000
- Use for non-R&D activities. (e.g., regulatory consultant)

CRO-type activities (Fee for service)

- Counted as small business direct costs.
- It is a commercially available service
- The small business does all analysis
- It is a fee per basis (no indirect costs by fee for service providers)

TECHNICAL & BUSINESS ASSISTANCE (TABA)

TABA Programs help small businesses identify and address their most pressing product development needs

	Applicant requests TABA Funds (at time of submission)	0	R Applicant uses NIH-provided TABA services
Phase I	 TABA Funding Up to \$6,500 for Phase I to use your own vendors Request as other direct costs (must include quote) in application, on top of \$400,000 budget cap 		 NIH-vetted third party company prepares an unbiased assessment of areas critical to success (IP/barriers to entry; market needs/competitive advantages; regulatory, manufacturing, and/or clinical plan; business model profitability
Phase II	 TABA Funding Up to \$50,000 across all years for Phase II to use your own vendors Request as other direct costs (must include quote) in application, on top of \$2,000,000 budget cap 		 TABA Consulting Services NIH-vetted third party identifies vendors to provide consulting services worth up to \$50,000 in one of these areas: IP, market analysis, regulatory, or reimbursement strategy and services

TIP #5. TALK TO A PROGRAM DIRECTOR

Send us your specific aims page: https://sbir.cancer.gov/



Michael Weingarten, MA Director

Webinar



Greg Evans, PhD Lead Program Director

Cancer Biology, E-Health, Epidemiology, Research Tools



Sarra Djemil, PhD **Program Director**

Therapeutics & Mentoring



Phase IIb Bridge

Cancer Biology, Biologics, Small

Molecules, Cell Based Therapies,

Jonathan Franca-Koh, PhD, MBA Lead Program Director



Monique Pond, PhD Lead Program Director

Biologics, Small Molecules, Therapeutic Devices, Digital Health, **Regulatory Resources**



Jian Lou, PhD **Program Director**

In-Vitro Diagnostics, Theranostics, early-stage drug development, Bioinformatics, Investor Initiatives



I-Corps

Saroj Regmi, PhD Program Director

Therapeutics, Diagnostics, Imaging,

Digital Health, Investor Initiatives,

Small Business Transition Grant,

William Bozza, PhD

Program Director

Therapeutics, Biologics, Small Molecules,

Regulatory (CMC), Concept Award, PLAN



Therapeutics, Biologics, Small Molecules, diagnostics, devices, and Regulatory (CMC and Nonclinical))

Patricia Weber, DrPH Program Director

Digital Health, Therapeutics, AAP, Investor Initiatives



Melissa Li, PhD

Therapeutics, Small Molecules,

Digital Health, AAP

Program Director

Ming Zhao, PhD **Program Director**

Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells



Linda Zane, PhD **Program Director**

Therapeutics, Diagnostics, Research Tools

STAY IN TOUCH!



Small Business Funding - Commercialization - Portfolio - Events About -





https://sbir.cancer.gov



Search

https://www.linkedin.com/company/ nci-sbir-development-center/







THANK YOU

CONTACT INFO NCI SBIR DEVELOPMENT CENTER <u>ncisbir@mail.nih.gov</u> 240.276.5300



SBIR DEVELOPMENT CENTER

