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<https://forms.gle/Z1qKgjVTLCpUF52Q8>



Join the Conversation: [@ncats_nih_gov](https://twitter.com/ncats_nih_gov) | [#NCATSsbir](https://twitter.com/NCATSsbir)

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NCATS

COLLABORATE. INNOVATE. ACCELERATE.

Entrepreneurial and Product Development support for Academic and Small Business Innovators

August 30, 2023



Hosts

NCATS

COLLABORATE. INNOVATE. ACCELERATE.

NCATS Office of Strategic Alliances
ncats.nih.gov/smallbusiness

The SBIR and STTR programs support NCATS' mission to **transform the translational science process so that new treatments and cures for disease can be delivered to patients more efficiently**. These programs serve as an engine of innovation, offering grants, contracts and technical assistance to small businesses and research organizations focused on advancing translational research and technologies that will improve disease prevention, detection and treatment.

NIH NATIONAL CANCER INSTITUTE

NCI SBIR Development Program
sbir.cancer.gov

NCI's Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs support small businesses across the United States to develop innovative cancer technologies with strong potential to help people live longer, healthier lives.

NCATS
COLLABORATE. INNOVATE. ACCELERATE.



National Heart, Lung,
and Blood Institute

NHLBI Small Business Program
nhlbi.nih.gov/

The NHLBI is interested in Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) activities that advance the prevention, diagnosis, and treatment of heart, lung, blood, and sleep disorders. Below is a list of funding opportunity announcements that offer small business entrepreneurs a chance to obtain funding without requirements to give up equity or ownership for early-stage research and development.



National Institute on Aging

NIA Small Business Programs
nia.nih.gov/research/sbir

The NIA Small Business Programs manage the largest source of early-stage funding for aging-related research and development (R&D). Each year, NIA provides more than \$140 million in R&D grants to small businesses through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. NIA has an unprecedented R&D budget to develop interventions that prevent or treat Alzheimer's disease (AD) and AD-related dementias.

Hosts



Center for Technology Commercialization

<https://wisconsinctc.org/>

Center for Technology Commercialization is here to help you to bring your innovative idea to market through access to our suite of programs and expert consultants in Wisconsin. CTC helps clients improve federal funding SBIR/STTR success rates, develop and enhance their competitive advantages and access resources from ideas to market and beyond.



BioForward's Women in Biohealth

<https://www.bioforward.org/women-in-biohealth/>

Women in Biohealth (WiB) was started in the fall of 2017 to provide a platform to empower and connect women in the biohealth community. Biohealth encompasses biotech, medical devices, digital health, diagnostics, and medical research. We are currently not a nonprofit organization but are utilizing BioForward, an association representing Wisconsin's biohealth industry, as our fiscal agent and marketing entity.

Featured Speakers



Margaret Ramey

Interim Director
Wisconsin Center for Technology
Commercialization



April Hughes

Sr HR Business Partner
BioForward's Women in Biohealth



Meena U. Rajagopal, Ph.D.

Program Officer
Office of Strategic Alliances
National Center for
Advancing Translational Sciences
National Institutes of Health



Stephanie Davis, Ph.D.

Small Business Program Coordinator
NHLBI

Featured Speakers



Joshua Hooks, Ph.D.

Program Officer
Office of Strategic Extramural
Programs (OSEP)
NIA



Saroj Regmi, Ph.D.

Program Director
SBIR Development Center
NCI



Monique LaRocque, M.P.H.

Executive Vice President
Ogilvy Health | FKH

MODERATOR



Agenda

Introductions and Objectives

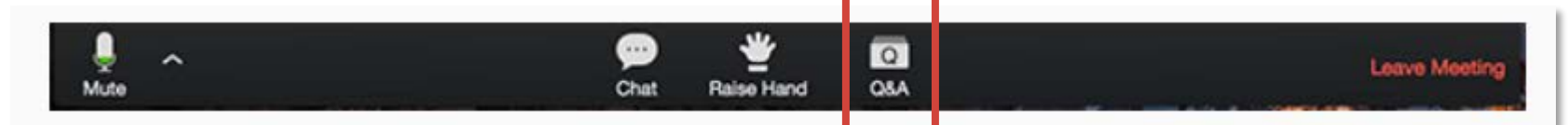
CTC Wisconsin & BioForward's Women in Biohealth

SBIR & STTR Programs

- NCATS
- NHLBI
- NIA
- NCI

Moderated Q&A

- Please use the Q&A function to submit questions at any time during the presentation

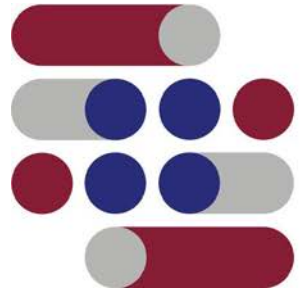




Margaret Ramey

Interim Director

Wisconsin Center for Technology Commercialization



Center for Technology Commercialization

Wisconsin's No-Cost SBIR/STTR Resource



<https://wisconsinctc.org/>





Proposal Prep:

Up to \$9K in grants to hire a grant or commercialization plan consultant



Proposal Review:

No-cost Panel Review for actionable feedback before agency deadline



Just In Time (JIT) Paperwork Support:

Contact us for assistance with completing JIT paperwork



Post Award Support:

Up to \$275K in Matching grants over Phase I and Phase II of project

Services for SBIR strategy, proposal prep, and submission



Upcoming CTC Wisconsin Events

NSF SBIR/STTR – Planning the Project - Webinar

September 13, 2023

Moving Your Tech Out of Academia – Panel Event

September 28, 2023

NSF Project Description Elements – Webinar

October 4, 2023

SBIR Advance Matching Grant

LOI due October 17, 2023

<http://bit.ly/CTCNewsletter>

CTC is Your Free Resource Concierge



Programs

On Demand Learning

Business Impact

About

Request for Counseling



<https://wisconsinctc.org/>

CTC@lists.Wisconsin.edu



April Hughes
Sr HR Business Partner
BioForward's Women in Biohealth

○ ○ ○ ○



**WI Women
in Biohealth**

○ ○ ○ ○

WHAT IS

The logo for WI Women in Biohealth features a stylized map of Wisconsin in blue and green, with a yellow molecular structure overlaid. To the right of the map, the text 'WI Women in Biohealth' is displayed in a sans-serif font, with 'WI' in blue, 'Women' in grey, and 'in Biohealth' in grey.

Mission

To provide a platform to empower and connect women in the biohealth community, deliver opportunities for professional and leadership development, and to facilitate career mentoring.

Affinity Group

- Not its own nonprofit!
- No membership requirements or dues
- Connected with BioForward but WiB members do not need to be BF members

Engagement

- Professional Development events
- Networking events
- Mentoring Program
- Circles
- LinkedIn- 574 members
- Email list- 637

Recent Updates

- Desire to give back to the female STEM community
- 4 groups formed- community outreach, advocacy, mentoring, prof. dev & networking

STEERING COMMITTEE



Lisa Johnson
CEO, BioForward



Christina Thomas-Virrig
Director Translational
Research, UW-Madison



Margaret Elvekrog
Corp. Strategy Manager,
Exact Sciences



Michele Smith
Program Manager,
MS-Biotech Program



Kate Rodgers
Global Healthcare Brand
Leader, GE Healthcare



April Hughes
Sr HR Business
Partner



Grace Maass
Executive Admin.
Asst., URP



Rissa Guffey
Marketing,
BioForward



Maci Camara
Member Engagement
Marketing Associate,
BioForward



THANK YOU



CONNECT



womeninbiohealth.org



[@bioforwardwi](https://www.linkedin.com/company/bioforwardwi)



sign up on our webpage





Meena U. Rajagopal, Ph.D.
Program Officer
Office of Strategic Alliances
National Center for Advancing Translational Sciences
National Institutes of Health

What Does the National Center for Advancing Translational Sciences (NCATS) Do?

1 of 27

Institutes and Centers at the National Institutes of Health (NIH).

Conducts and supports research on the science and operation of translation to allow more treatments to get to more patients more quickly.



Focuses on what is common across diseases and the translational process.

NCATS

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

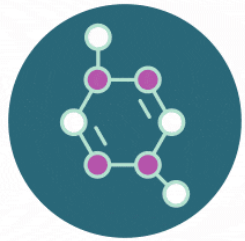


Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

TRANSLATIONAL SCIENCES

Re-engineering the Translational Pipeline

NCATS addresses long-standing bottlenecks in the translational research pipeline so that new treatments reach people faster.



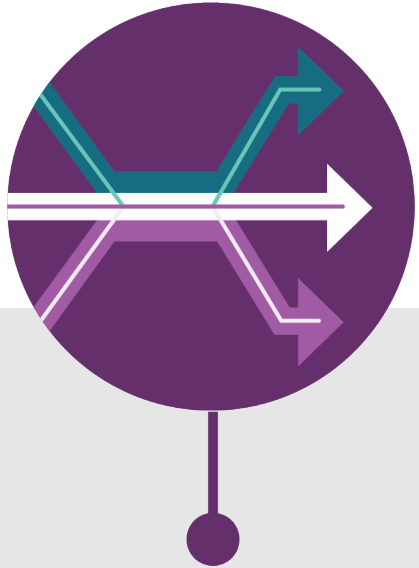
Bottlenecks:

- Incompatible databases
- Administrative burden for study start-up
- Insufficient tools and technologies to predict toxicity and efficacy of new drugs

NCATS Solutions:

- Data interoperability and integration
- Streamlined business processes
- Models that mimic the structure and function of human tissues

Key NCATS Approaches



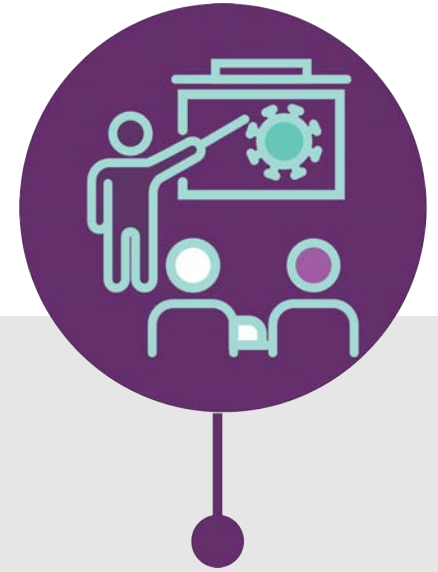
Understanding what's similar across diseases to spur multiple treatments at a time



Developing models that better predict a person's reaction to a treatment



Enhancing clinical trials so the results more accurately reflect the patient population



Leveraging real-world data and data science approaches to address public health needs

NCATS Scientific Initiatives

Clinical Translational Science

- Clinical and Translational Science Awards
- Rare Disease Clinical Research Network
- New Therapeutic Uses program

Preclinical Translational Science

- NCATS Chemical Genomics Center
- Therapeutics for Rare and Neglected Diseases program
- Bridging Interventional Development Gaps program

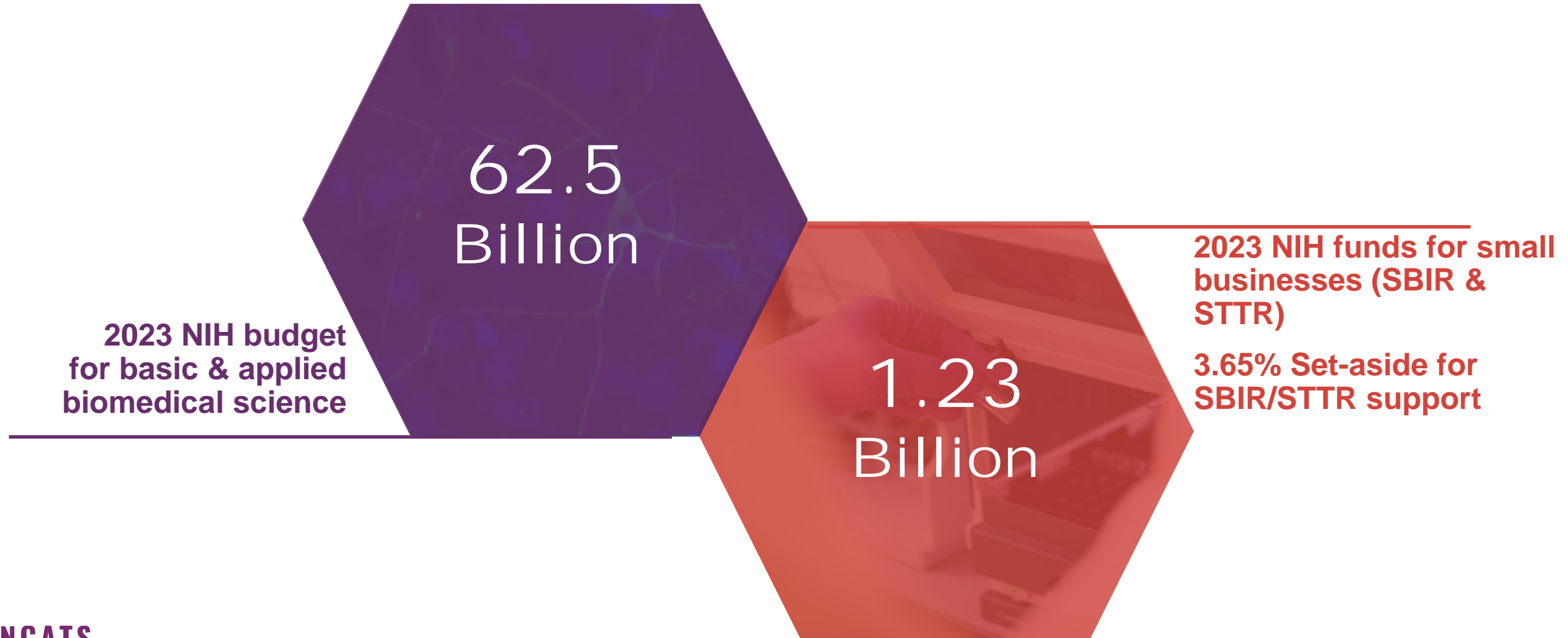
Re-engineering Translational Sciences

- Toxicology in the 21st Century
- Microphysiological Systems (Tissue Chip) program
- Office of Rare Diseases Research



NCATS Small Business Program

SBIR and STTR: One of the Largest Sources of Early-Stage Financing



The Benefits

NCATS SMALL BUSINESS PROGRAMS (SBIR/STTR)

**Stable and predictable.
Not a loan. Funds don't
have to be repaid.**



**Non-dilutive. IP rights are
retained by the small
business.**



**Technical assistance to
advance and commercialize
technologies for public
good.**



Projects undergo NIH's rigorous scientific peer review process, which awardees leverage to attract other funding and collaborations.



Who Is Eligible for SBIR Funding?

Criteria for applying to SBIR:

- ✓ U.S. businesses with **500 or fewer employees**
- ✓ **PI Primary employment with small business** at the time of the award and duration of the project
- ✓ **More than 50% U.S.-owned** by individuals and independently operated

OR

More than 50% owned and controlled by other business concern(s) that is/are > 50% owned and controlled by one or more individuals

OR

More than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms or any combination of these



Who Is Eligible for STTR Funding?

Criteria for applying to STTR:

- ✓ **An established cooperative research and development effort delineated as:**
 - Minimum 40% by small business concern; minimum 30% by U.S. college or university, non-profit research organization or Federally-Funded R&D Center (FFRDC)
- ✓ **Formalized intellectual property agreement**
 - Should provide the necessary IP rights in order to carry out follow-on R&D and commercialization
- ✓ **Primary employment of the principal investigator with either the small business or research institution**

SBIR and STTR Critical Differences

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g., university)
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business

Award is always made to the small business

Special Designations



- Encouraging participation in innovation and entrepreneurship by socially and economically disadvantaged small businesses (SDB) and women-owned small businesses (WOSB).
- What is a **Socially and Economically Disadvantaged Small Business** (SDB)?
 - The firm must be 51% or more owned and control by one or more disadvantaged person or persons.
 - The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged.
 - The firm must be small, according to SBA's **size standards**.
 - Small businesses must self-certify by registering in the **System for Award Management**.
- What is a **Women-Owned Small Business** (WOSB)?
 - A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women (who must be U.S. citizens).
 - The firm must be “small” in its primary industry in accordance with SBA’s size standards for that industry.
 - SBCs self-certify on the Sam.gov.

NIH SBIR/STTR Is a Three-Phase Program



Phase I Feasibility Study

Budget Guide: \$295,924 for SBIR and STTR (*\$350K Waiver*)
Project Period: 6 months (SBIR); 1 year (STTR)



Phase II Full Research/R&D

\$1,972,828 for SBIR and STTR, over two years (*\$2.15M Waiver*)

Fast Track combines Phase I and Phase 2
Direct to Phase 2 – allows to skip Phase 1

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/to FDA
Funding Varies (~\$1M per year) for up to 3 years



Phase III Commercialization

NIH, generally, not the “customer”
Consider partnering and exit strategy

Funding Overview

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are some of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow U.S.-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

Omnibus Solicitation

- Investigator-initiated grant funding
- Standard Deadlines: January 5, April 5, September 5

Grant Solicitations in Targeted Areas

- Grant to advance a particular technology/research area
- Due dates may vary

Contract Solicitation

- Contract opportunity to advance areas of high research interest
- Typically due in October or November

Commercialization Readiness Pilot

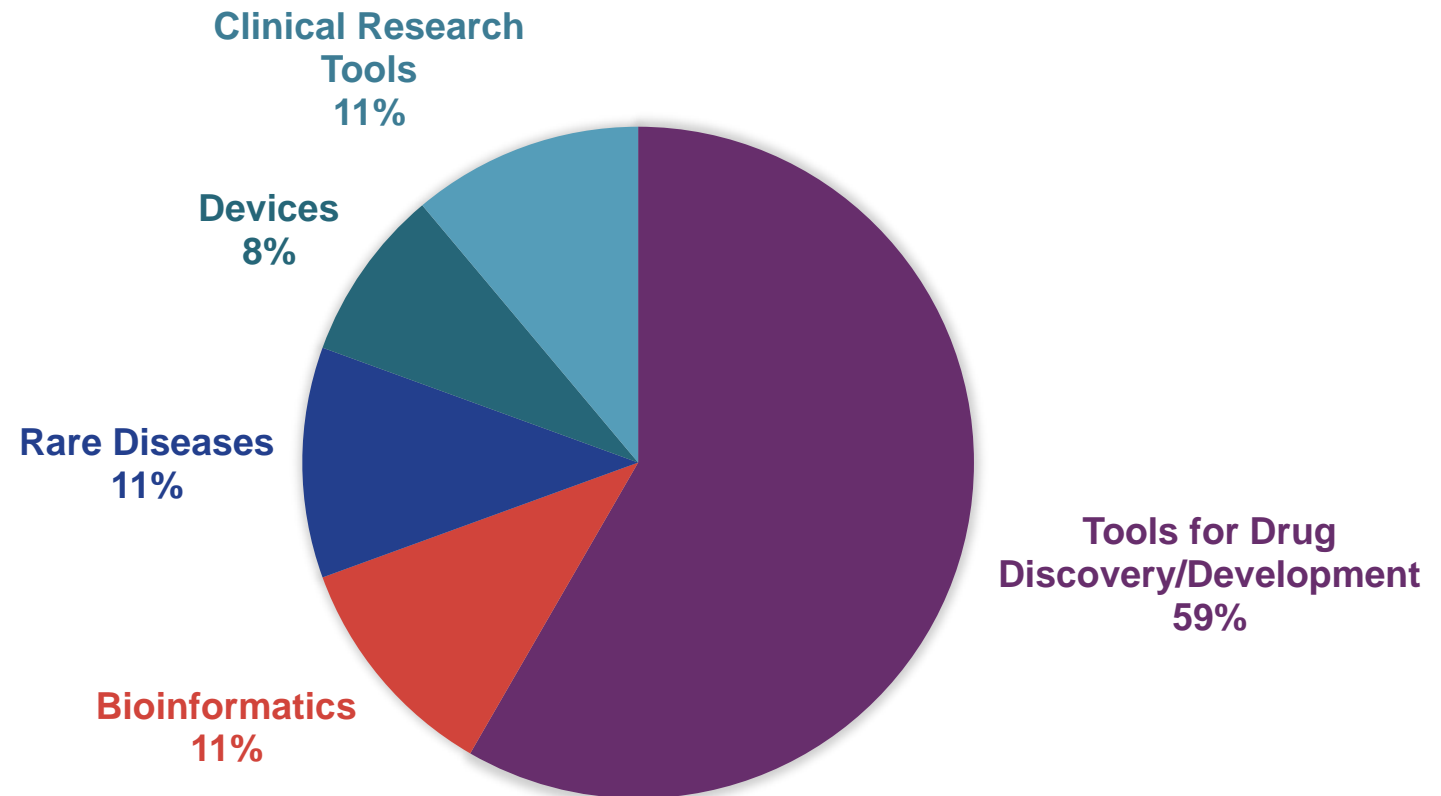
- Provides additional technical assistance and late-stage R&D support not typically covered within small business awards.
- Standard Deadlines

Translational Science and Research Areas of Interest

SBIR and STTR programs support NCATS' **mission to transform the translational science process** so that **new treatments and cures** for disease can be **delivered to patients more efficiently**.

TOPICS OF INTEREST

1. Preclinical Drug Discovery & Development
2. Biomedical, Clinical & Health Research Informatics
3. Clinical, Dissemination & Implementation Research



Targeted Funding Opportunities for 2023

- **Innovations for Healthy Living - Improving Minority Health and Eliminating Health Disparities**
 - SBIR: [RFA-MD-23-003](#) (R43/R44 - Clinical Trial Optional)
 - Next Deadline: Sept. 6, 2023
- **Technologies for Improving Minority Health and Eliminating Health Disparities**
 - STTR: [RFA-MD-23-002](#) (R41/R42- Clinical Trial Optional)
 - Next Deadline: Sept. 6, 2023
- **NHLBI SBIR Phase IIB Small Market Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44 Clinical Trial Optional)**
 - [SBIR: RFA-HL-23-008](#)
 - Next Deadline: Feb. 28, 2024
- **Industrialization and Translation of Extracellular Vesicles for use in Regenerative Medicine**
 - SBIR: [PAR-23-267](#) (U43/U44 Clinical Trials Not Allowed)
 - STTR: [PAR-23-268](#) (UT1/UT2 Clinical Trials Not Allowed)
 - Next Deadline: June 6, 2024

NIH & CDC SBIR Contract Solicitation (PHS-2024-1)

The **FY24 SBIR contract solicitation** has been released.

The solicitation lists **specific need areas** (referred to as Contract Topics). To submit a contract proposal, your small business **must respond to one of these topics**.

[View the solicitation](#) (PHS-2024-1) and learn about the [differences between grants and contracts](#).

Proposals are due by Tuesday, Nov. 14, 2023, at 05:00 p.m. EDT.

There will be an informational webinar on Wednesday, September 27, at 1 p.m. EDT. Mark your calendars and stay tuned for more information!

Application Process Timeline

Due Dates	Scientific Review	Council Review	Award Date (Earliest)
SEPTEMBER 5	OCTOBER/NOVEMBER	JANUARY/FEBRUARY	MARCH/APRIL
JANUARY 5	FEBRUARY/MARCH	MAY/JUNE	JULY
APRIL 5	JUNE/JULY	AUGUST	SEPTEMBER OR DECEMBER

A photograph of three scientists in a laboratory setting, overlaid with a blue tint. The scientists are wearing white lab coats and safety glasses. The man on the left has a name tag that says "Aashish" and a Sandia National Laboratories logo. The woman in the center is holding a pipette. The man on the right is looking down at something in his hands. The background shows laboratory equipment and shelves.

SBIR & STTR

DEVELOPING A COMPETITIVE APPLICATION
Tips for Success

Scored Review Criteria

SIGNIFICANCE

Does the product address an important **problem**, and have commercial potential? Is there a market pull for the proposed product?

APPROACH

Are **design and methods** well-developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?

INNOVATION

How novel is the **technology/product** and the **approaches** proposed to test its feasibility? What is the competitive advantage?

INVESTIGATOR

Are the investigators, collaborators and consultants appropriately trained and **capable** of completing all project tasks?

ENVIRONMENT

Does the **scientific environment** contribute to the probability of success? **Facilities? Independence?**

COMMERCIALIZATION

Is the company's **business strategy** one that has a high potential for success?

Electronic Grant Application Submission

SBIR/STTR applications must be submitted electronically.

Registrations are required; **START EARLY**

- Unique Entity Identifier Number (SAM) System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov

Establish your [Login.gov account](#) and [sign up](#) for UEI (formerly DUNS), SAM.gov, Grants.gov, eRACommons, and SBA Registry as soon as possible to avoid delays. It can take 4-6 weeks to complete all registrations.

<http://era.nih.gov/applicants/index.cfm>



Top Tips

- **Review Notice of Funding Opportunities (NOFOs)**

Its important to review the NCATS research topics of interest and eligibility carefully, make sure that your area of focus aligns with NCATS areas of interest

1. **Review sample applications:**

- NIA: <https://www.nia.nih.gov/research/osbr/nia-small-business-sample-applications>
- NIAID: <https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44>
- NCI: <https://sbir.cancer.gov/resources/forapplicants#Sample>

2. **Do your homework** on NIH funded applications – NIH RePORTER: <http://projectreporter.nih.gov>

3. **Talk to an NIH Program Officer** about your application: <https://sbir.nih.gov/engage/ic-contacts>

- Contact an appropriate NIH Program Director in advance (**at least 1 month before due date!**), to discuss your specific aims and receive feedback
- Before submitting an application, share abstracts to get feedback from program officers about your idea

4. **Register early** for SBIR or STTR electronic submission process

5. Use [NIH ASSIST](#) to **streamline the application process**

- [Annotated FORMS-H](#) & [SF424 Form-H Instructions](#)

6. **Specify** the Institute and study section for which you're applying

7. **SUBMIT EARLY** (days not hours and minutes)

7 Tips



Important Facts to Remember

- Eligibility is determined at **time of award**
- PD/PI is **not** required to have a Ph.D./M.D.
- PD/PI is required to have expertise to oversee project scientifically and technically
- Applications **may be** submitted to **different agencies** for similar work to support different aims/objectives
- Awards may not be accepted from different agencies **for duplicative projects**



Communication After Review

Rejection is painful, but:

- Understand the review process and dynamics:
www.csr.nih.gov/
- Discuss Summary Statement with your NIH Program Officer
- Be open to reviewer critiques; be constructive not defensive in your response
- Consider reapplying, but spend A LOT of time reading and revising your aims page.



Additional Small Business Resources

Commercialization Readiness Pilot (CRP)

CRP provides additional technical assistance and late-stage research and development support not typically covered within small business awards to help products get to market.

- **Technical Assistance and Late-Stage Development**
- SBIR/STTR SB1: ([PAR-23-219](#)) - Clinical Trial Not Allowed (\$3,421,062 total funding support for up to 3 years)
 - *Note on NIA Participation:* [NOT-AG-23-047](#)
 - Next Deadline: Sept. 5, 2023
- **Technical Assistance and Late-Stage Development**
 - SBIR/STTR ([PAR-23-220](#)) - Clinical Trial Required (\$3,421,062 total funding support for up to 3 years)
 - *NCATS does not accept applications with clinical trials*
 - *Note on NIA Participation:* [NOT-AG-23-048](#)
 - Next Deadline: Sept. 5, 2023

Eligibility

- Small businesses with an active NIH SBIR or STTR Phase II or Phase IIb contract or grant within the last 36 months.
- Only 1 CRP is allowed per project.
- Companies have the option of out-sourcing a significant portion of the work requested through the CRP, provided the expert services are appropriate for the work proposed and well justified in the application.



Standard due dates apply.

Crossing the “*Valley of Death*” with the NCATS Therapeutic Development Team



- Medicinal chemistry lead optimization
- Evaluation of functional activity, potency, pharmacokinetics (PK), pharmacodynamics (PD), and efficacy
- Biomarker development
- Definition and optimization of dose and schedule for *in vivo* activity
- Development and implementation of pharmacological assays
- Chemical and biologics process research and development
- Manufacturing of bulk substance (GMP and non-GMP)
- Development of suitable formulations
- Development of analytical methods
- Production and stability studies of dosage forms
- Range-finding initial toxicity
- Investigational New Drug (IND)-directed toxicology, with correlative pharmacology and histopathology
- Planning of clinical trials (Phase 1 and/or Phase 2)
- Regulatory and IND filing support
- Natural history and patient-finding studies

NCATS Additional Resources: Bridging Interventional Development Gaps (BrIDGs)

Model: Collaboration between Division of Preclinical Innovation (DPI) and extramural labs (Formerly NIH-RAID Program)

Projects

- Enter with clinical candidate identified
- Any disease eligible
- Gap analysis followed by data generation using DPI resources and expertise to generate data necessary for IND filing

Eligible Applicants

- Academic (U.S. and Ex-U.S.), Non-Profit, SBIR-eligible businesses

The program is accepting applications - **Due date** Sep 30, 2023



NCATS Additional Resources: Therapeutics for Rare and Neglected Diseases (TRND) Program

Model: Comprehensive drug development collaboration between DPI and extramural labs with disease-area/target expertise

Projects

- May enter at various stages of preclinical development
- Disease must meet FDA orphan or WHO neglected tropical disease criteria
- Taken to stage needed to attract external organization to adopt to complete clinical development/registration, max Phase 2a
- Milestone driven
- Therapeutic modalities: small molecules, proteins, peptides, oligonucleotides, gene therapy, antibodies, recombinant proteins
- Aims to de-risk technology and develop new generally applicable platform technologies and paradigms

Eligible Applicants

- Academic, Nonprofit, Government Lab, Biotech/Pharma
- Ex-U.S. applicants accepted



Connect with NCATS



Website: ncats.nih.gov



Facebook: facebook.com/ncats.nih.gov



LinkedIn: linkedin.com/company/nih-ncats/



Twitter: twitter.com/ncats_nih_gov



YouTube: youtube.com/user/ncatsmedia



E-Newsletter: ncats.nih.gov/enews



Listserv: bit.ly/1sdOI5w

Questions?

- NCATS-SBIRSTTR@mail.nih.gov





National Institute of Minority Health Disparities SBIR/STTR Health Disparities Program

CDR Michael Banyas, USPHS, MPA, MA NIMHD
SBIR/STTR Program Manager

michael.banyas@nih.gov



National Institute
on Minority Health
and Health Disparities

NIMHD Program Goals

Disease agnostic

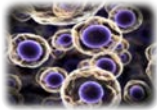
Focus not drugs, but devices, services, digital health, and other means to close health equity gaps

- 1) Promote research to understand and to improve the health of racial/ethnic minority populations
- 2) Advance scientific understanding of the causes of health disparities
- 3) Develop and test interventions to reduce health disparities
- 4) Create and improve scientific methods, metrics, measures, and tools that support health disparities research

Mechanisms Leading to Health Disparities



Individual Behaviors, Lifestyle, Beliefs and Attitudes: Racism, childhood adverse conditions, food insecurity, witness to or victim of violence, immigrant, limited English proficiency, response to chronic stress



Biological Processes and Genetics: Earlier age of onset, gene variants, metabolic differences, susceptibility, faster progression or greater severity, brain networks, microbiome, extracellular RNA, sleep



Physical and Cultural Environment: Place, social system, neighborhood, infrastructure, family, social interactions, network, community cohesion



Clinical Events and Health Care: Differential treatments, poor communication, adverse drug events, falls, progression of disease, access and use/abuse of appropriate services, end-of-life care



NIH Health Disparity Terms and Recognized Populations

Health Disparities Recognized Populations
Hispanics/ Latinos
Rural areas
American Indians/ Alaska Natives
Sexual/gender minorities
Socio economically disadvantaged individuals
African Americans/ Blacks
Native Hawaiians and Other Pacific Islanders
Asians

Buckets Identified as Barriers for Health Equity
Physical
Knowledge
Infrastructure
Economic
Cultural

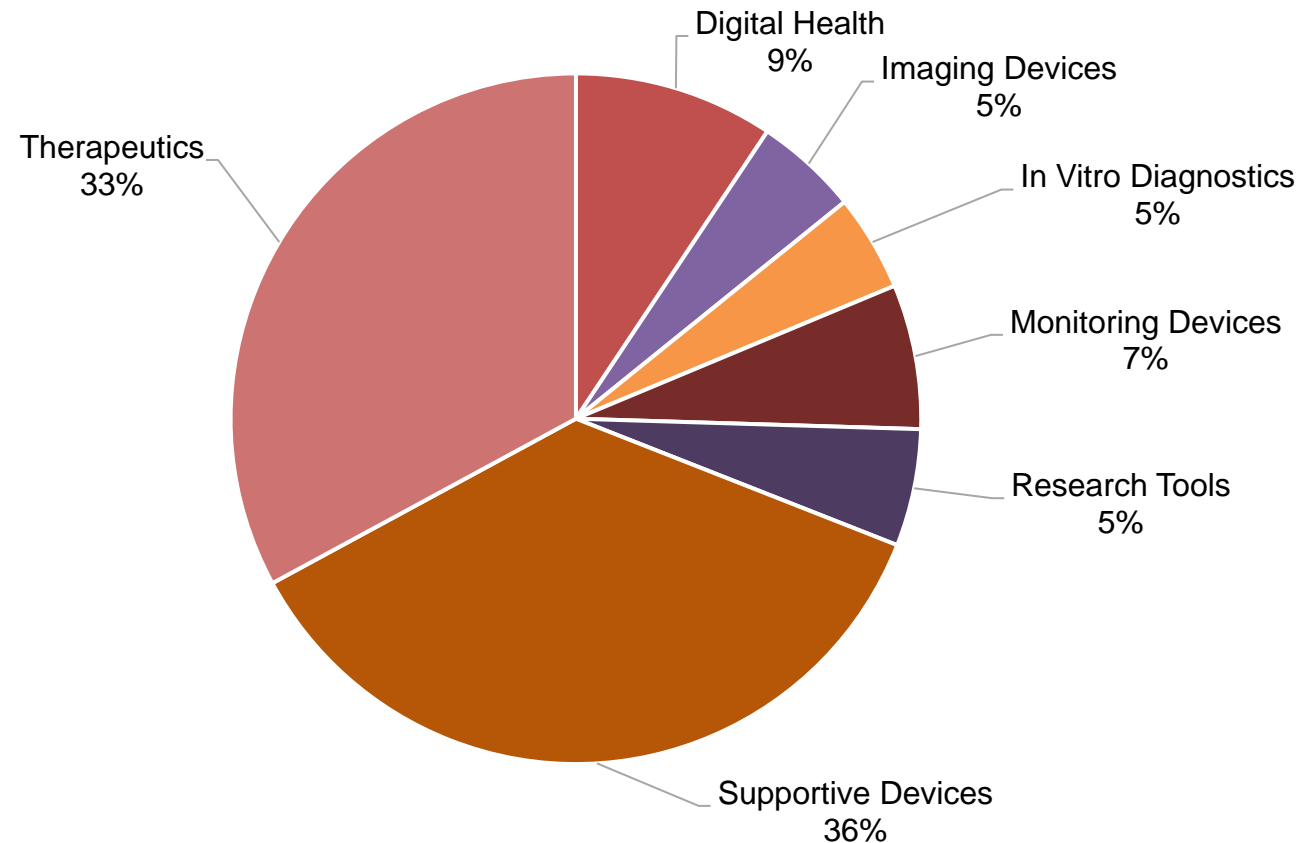


Stephanie Davis, Ph.D.
Small Business Program Coordinator
NHLBI

The NHLBI Small Business Program

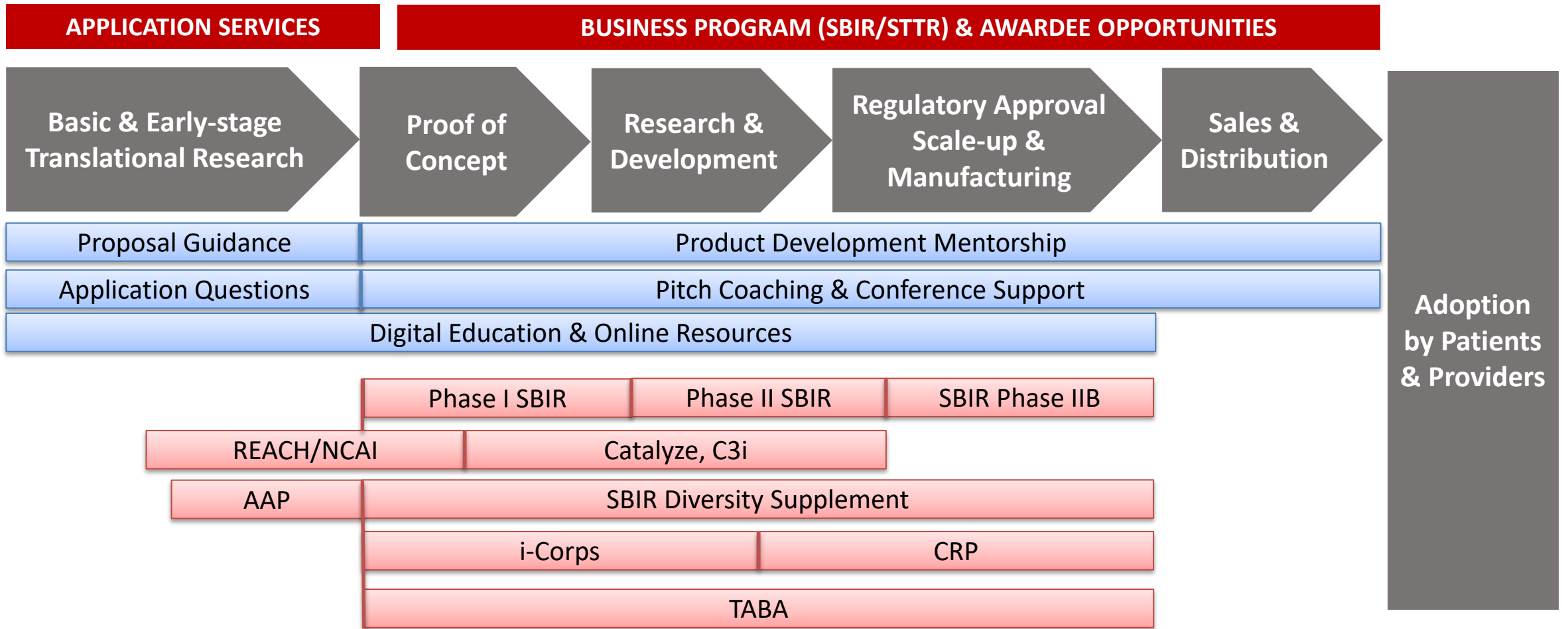
Innovative and commercially-promising products to prevent, treat and diagnose **heart, lung, blood, and sleep (HLBS)-related diseases**

Technologies Funded by the NHLBI SBIR/STTR Program



n = 328

NHLBI I&C Programs and Services & Timing



● Services & Activities ● Grant Programs/ Supplements

NHLBI Targeted Funding Opportunity Announcements

Funding Opportunity	FOA #
Phase IIB Bridge Awards	➤ RFA-HL-23-009
Phase IIB Small Market Awards	➤ RFA-HL-23-008
HEAL Initiative: Technologies Directed at Enhanced Pain Management	➤ RFA-NS-23-006 ➤ RFA-NS-23-007
Innovations for Healthy Living - Improving Minority Health and Eliminating Health Disparities (R43/R44 - Clinical Trial Optional)	➤ RFA-MD-23-003
NOSI: Small Business Initiatives for Innovative tools and Technologies for Improving Outcomes for Maternal Health	➤ NOT-EB-23-005
NOSI: Improving Patient Adherence to Treatment and Prevention Regimens to Promote Health	➤ NOT-OD-21-100
NOSI: Validation of Digital Health and Artificial Intelligence Tools for Improved Assessment in Epidemiological, Clinical, and Intervention Research	➤ NOT-CA-22-037
NOSI: Development of Functional Assay Sites to Evaluate Candidate -Omics Variants Associated with Heart, Lung, Blood, or Sleep Disease	➤ NOT-HL-23-066

Phase IIB Bridge (HL-23-009) and Small Market (HL-23-008) RFAs

Purpose of the Programs

- Provide innovators who are developing technologies focused on heart, lung, blood, or sleep-related condition with support to meet regulatory milestones and connect with investors/strategic partners
- Bridge Program designed for all technologies that fall under the NHLBI mission
- Small Market Program designed for technologies that address rare diseases and/or pediatric indications

Budget

- Up to \$3M total costs over 3 years
 - 1:1 Matching Funds Expected for Bridge Awardees
 - 1:3 Matching Funds Expected for Small Market Awardees

Approximate Number of Awards Per Year

- Five (5) Bridge Awards
- Two (2) Small Market Awards

Next Receipt Date: **February 28th, 2024**

RFA-MD-23-003: Innovations for Healthy Living SBIR RFA

- Focused on developing a commercialized technology or service to improving minority health and/or reducing and ultimately eliminating health disparities
- The NHLBI is interested in funding the development of the following technologies to improve HLBS health in historically underserved, low-resource, and remote communities
 - Informatics devices
 - Diagnostic devices/tools
 - Wearable technologies
 - Mobile applications
- Differences from the Omnibus NOFOs
 - Set-aside funds
 - NIMHD Special Emphasis Panel
- Next Due Date: **September 6, 2023**



HEAL RFAs: Technologies Directed at Enhanced Pain Management

- Key Priority Area: Supporting the development of therapies and technologies directed at enhanced pain management through SBIR/STTR.
 - Research tools and models focused on pain and development of pain therapies
 - Advancing new non-addictive pain treatments through the clinical pipeline
 - Develop improved pain management strategies for acute and chronic pain conditions, including development of novel pain management technologies and devices, and objective pain measurement
- Differences from the Omnibus PAs
 - Set-aside funds from HEAL Initiative
 - Special Emphasis Panel
- Two Active RFAs
 - RFA-NS-23-006 (SBIR)
 - RFA-NS-23-007 (STTR)
- Next Due Date: **September 4, 2023**



Technical and Business Assistance (TABA)

Discovery Phase I



Feasibility

\$6.5K for Technical and Business Assistance-related expenses
(Request during application or through NOT-OD-21-062)

NIH-Administered [TABA Needs Assessment Program](#)

Development Phase II



Full R/D

\$50K for Technical and Business Assistance-related expenses
(Request during application)

NIH-Administered [TABA Consulting Services](#)

Examples of activities supported by TABA Funds

Assistance with product sales

Intellectual property protections

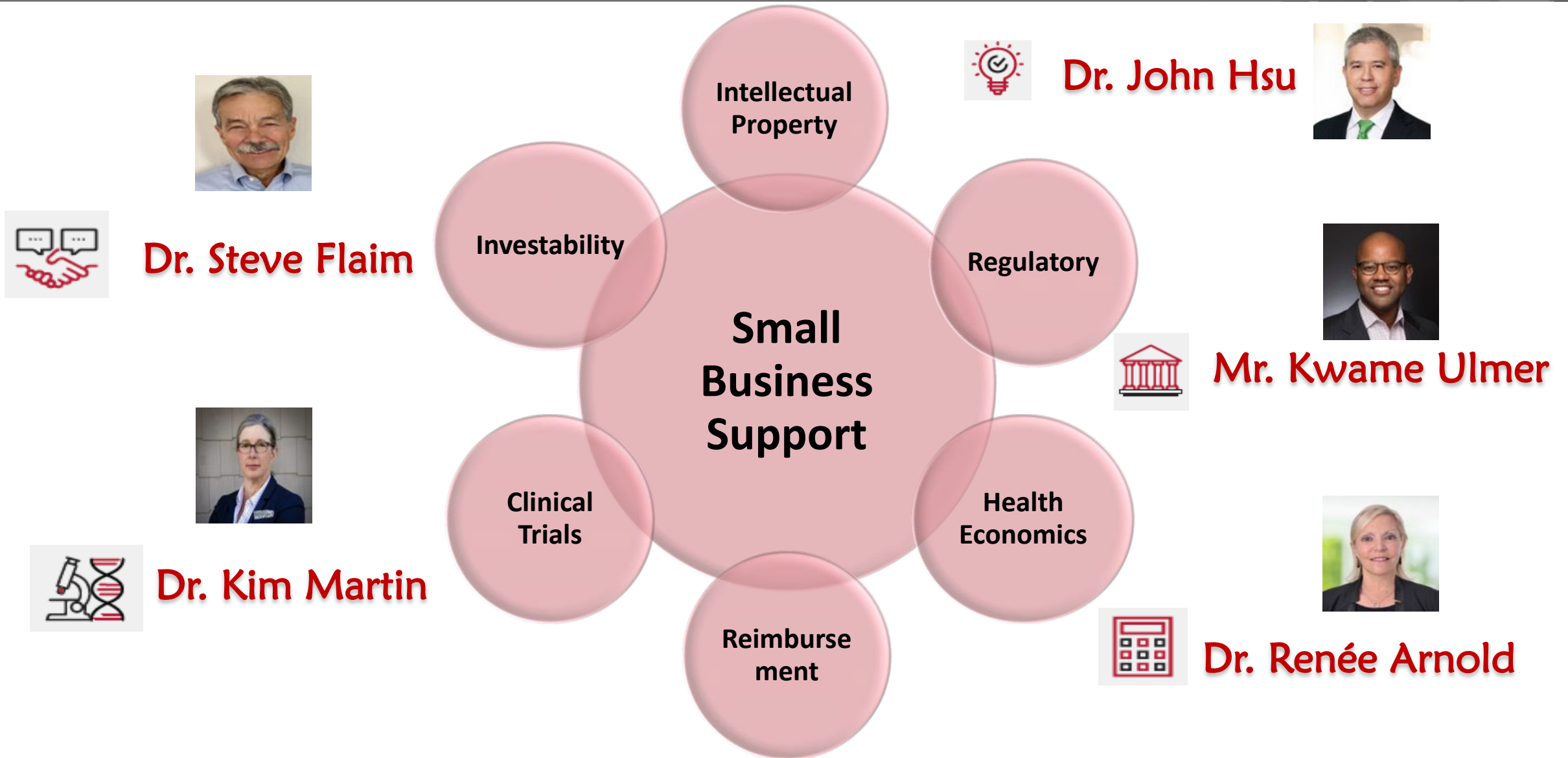
Market research and/or validation

Development of regulatory plans

Development of manufacturing plans

Access to technical and business databases

Entrepreneurial & Product Development Expertise



NHLBI Company Profile: Cellular Logistics

- Biotech company spun out from UW-Madison
- Developing therapeutic biomaterial called the cardiac fibroblast biomatrix (CFX™) to promote cardiac regeneration after acute myocardial infarction
- Awarded two SBIR Phase I awards from NHLBI
- Recently won \$850K SBIRAdvance grant from the State of Wisconsin

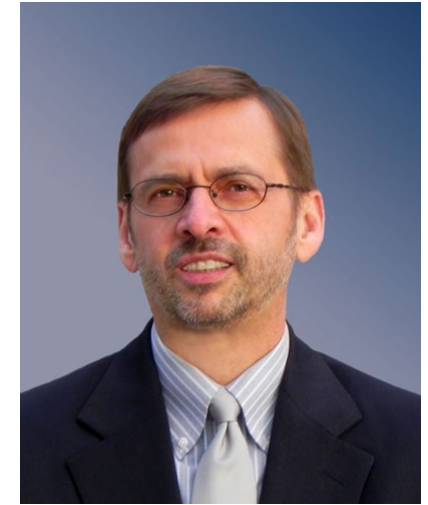


Eric G. Schmuck, Ph.D.
Co-Founder and CSO



NHLBI Company Profile: Pantherics

- Pharmaceutical company spun out from UW-Milwaukee and the Milwaukee Institute for Drug Discovery (MIDD)
- Developing GABA_A receptor agonist (PI-301) for the treatment of asthma
- Awarded SBIR Phase I awards from NHLBI
- Received the Healthcare Innovation Pitch Event grand prize during the 2022 Milwaukee Tech Week

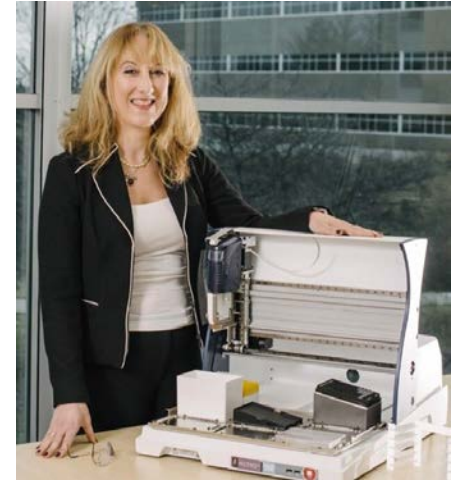


Doug Stafford, Ph.D., M.B.A.
Founder and CEO



NHLBI Company Profile: InVivoSciences

- Precision medicine-focused biotech company based in Madison, WI
- Developing novel tools to improve drugs screening and the development of therapeutics for heart failure
 - iPSC-derived microheart tissue (NuHeart™)
- Awarded SBIR Phase I and II awards from NHLBI and Phase I award from NIA
- Selected as 2020 RESI Innovation Challenge Winner



Ayla Annac, M.B.A.
Co-Founder and CEO

InVivoSciences

Product Definition Funding Opportunities

Next Application Deadline
November 21, 2023

Enabling Technologies

- Enabling Technologies and Transformative Platforms for HLBS Research R33 ([RFA-HL-23-010](#))

Small Molecules and Biologics

- Target Identification and Validation, Preliminary Product/Lead Series Identification R61/R33 ([RFA-HL-23-011](#))
- Preliminary Product/Lead Series Identification R33 ([RFA-HL-23-012](#))

Devices and Diagnostics

- Prototype Design and Testing, Diagnostic Disease Target Identification, Assay Development and Research Tool Dev. R61/R33 ([RFA-HL-23-013](#))
- Prototype Testing and Design Modification, Diagnostic Disease Target Assay Development, and Design Characterization, and Research Tool Testing and Validation R33 ([RFA-HL-23-014](#))

US-based academic, non-profit institutions, and US-owned for-profit institutions are eligible to apply



Connect with Us!

- Follow us on Twitter at [@NHLBI_SBIR](https://twitter.com/NHLBI_SBIR)
- Email us at NHLBI_SBIR@mail.nih.gov

Visit the I&C Website



Sign up for our I&C Newsletter





Joshua Hooks, Ph.D.

Program Officer

Office of Strategic Extramural Programs (OSEP)

NIA

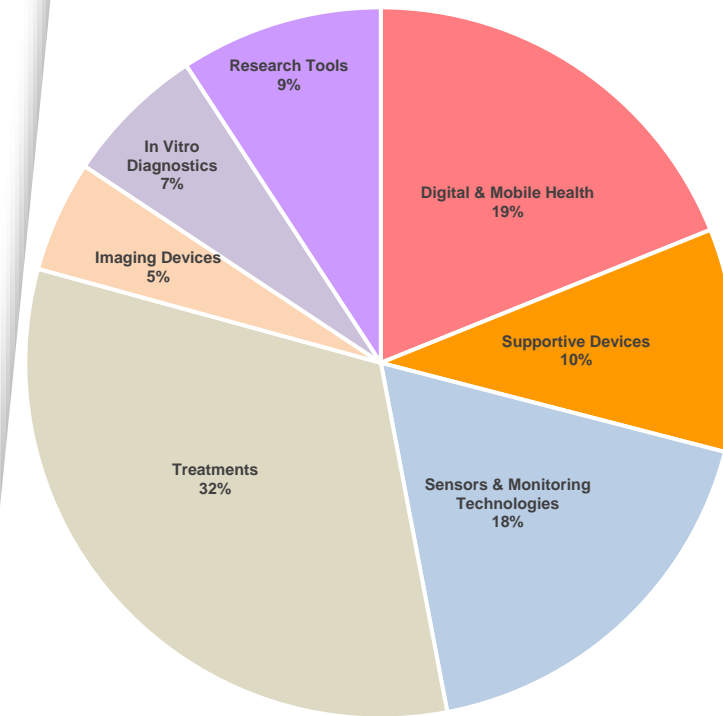
We Strategically Fund Innovations for:

- ❑ Alzheimer's disease (AD), AD-related dementias (ADRD), and age-related change in brain function
- ❑ Aging in place
- ❑ Age-related diseases and conditions
- ❑ Research tools

Additional Areas of Interest

- Companion diagnostics and other forms of personalized medicine
- Bioinformatics, public health informatics, or data science technologies/methods (e.g., machine learning, artificial intelligence) to better understand and predict health outcomes
- Novel cell and gene therapies, as well as other novel therapeutic approaches to AD/ADRD
- Biomarkers and diagnostic tools for the early detection of disease
- Prevention and therapeutics that directly target mechanisms related to aging biology
- Assistive technology, devices, and mobile applications for older adults and caregivers
- Tools, technologies, and analytic methods to address health disparities among older adults

Portfolio Classifications (AD & Non AD)



SBIR & STTR Program Phases and Funding Levels

Phase I	Discovery & Feasibility	<ul style="list-style-type: none"> • Typically 1 year in length • Awards up to \$400,000, or up to \$500,000 for AD/ADRD • Establish technical merit, feasibility, and potential for commercialization
Phase II	Development & Full R&D	<ul style="list-style-type: none"> • Typically 2 years in length • Awards up to \$2.25 million, or up to \$2.5 million for AD/ADRD • Continues Phase I R&D efforts • Requires a commercialization plan
Fast Track		<ul style="list-style-type: none"> • One combined application for Phases I and II
Direct-to-Phase II (SBIR only)		<ul style="list-style-type: none"> • Apply directly for Phase II funding • Demonstrated feasibility through other funding sources
Commercialization Readiness Pilot		<ul style="list-style-type: none"> • Funding for late-stage R&D and technical assistance for commercialization • Awards up to \$3.94 million
Phase IIB	Competing Renewal	<ul style="list-style-type: none"> • Up to 3 years • Awards up to \$3 million



Primary NIA Funding Opportunities

Investigator-Initiated Grants

1.

Omnibus Solicitation

3 receipt dates:
January 5 • April 5
September 5

Other Funding Opportunities

2.

Targeted Solicitations

Focused priority
areas with variable
receipt dates



NIA Funding Opportunities

	Omnibus FOA	Targeted FOA
	“General Aging”	AD/ADRD-Focused FOAs
SBIR	<p><u>PA-22-176</u> (clinical trial not allowed) <u>PA-22-177</u> (clinical trial required)</p> <p><i>Budget limits: Phase I \$400,000; Phase II \$2.25 million</i></p>	<p><u>PAS-22-196</u> (Advancing Research on AD/ADRD) <i>Budget limits: Phase I \$500,000; Phase II \$2.5 million</i></p>
STTR	<p><u>PA-22-178</u> (clinical trial not allowed) <u>PA-22-179</u> (clinical trial required)</p> <p><i>Budget limits: Phase I \$400,000; Phase II \$2.25 million</i></p>	<p><u>PAS-22-197</u> (Advancing Research on AD/ADRD) <i>Budget limits: Phase I \$500,000; Phase II \$2.5 million</i></p>

**Notice of Special Interest: Small Business Digital Technologies for Early Detection, Characterization and Monitoring of Senescence-Related Changes*



NIA Resources to Help Research Entrepreneurs

Early-Stage Entrepreneurs

NIA Research and Entrepreneurial Development Immersion (REDI): Multiple awards to prepare and expose early-career researchers to life science entrepreneurship

NIA Startup Challenge and Accelerator: Fostering Entrepreneurial Diversity. Provide training, mentoring, networking, and the opportunity for a cash prize for early-stage innovators from historically excluded backgrounds and founders working on health disparities in the older adult population

Applicants

Sample Applications. Review other [successful applications](#) on our website to see what information other applicants included and how they presented it.

Applicant Assistance Program. A [10-week coaching program](#) to help prepare your Phase I application. Open to first-time and never-funded applicants.

Phase I Awardees

Innovator Support. Support from the [NIA Entrepreneurs-in-Residence](#) including business consults, pitch coaching, company showcase opportunities and various supplemental awards (s.a. TABA funds and diversity supplement).

Additional Resources and Support for Grantees. Companies that receive SBIR/STTR awards are [eligible to apply](#) for additional funding, technical assistance, and training programs such as the I-Corps™ at NIH program, C3i Medical Device Entrepreneurial Training Program, and training programs designed for diverse applicants.



Research & Entrepreneurial Development Immersion (REDI)

- A series of Funding Opportunities aimed at:
 - Entrepreneurial training in NIA-mission areas
 - Allowing trainees to acquire additional non-academic skills



NIA Research and Entrepreneurial Development Immersion (REDI)

	FOAs	Due Dates	Budget Limits
SBIR	<u>RFA-AG-24-042</u> (REDI Entrepreneurial Small Business Transition Award; clinical trial optional) <i>Key Eligibility: Within 10 years of PhD, first time PI on R grant</i>	Letter of Intent: September 26, 2023 Application: October 26, 2023	Phase I \$500,000; Fast-Track \$2.5 million
STTR	<u>RFA-AG-24-043</u> (REDI Entrepreneurial Small Business Transition Award; clinical trial optional) <i>Key Eligibility: Within 10 years of PhD, first time PI on R grant</i>	Letter of Intent: September 26, 2023 Application: October 26, 2023	Phase I \$500,000; Fast-Track \$2.5 million
R25	<u>PAR-22-226</u> (REDI Entrepreneurship Enhancement Award; clinical trial not allowed)	Letter of Intent: 30 days before due date Applications: October 18, 2023 ; October 17, 2024	\$250,000/year in direct costs
K01	<u>PAR-22-227</u> (REDI Mentored Entrepreneurial Career Development Award; clinical trial not allowed) <i>Key Eligibility: Postdoctoral fellow, junior faculty/assistant prof.</i>	Letter of Intent: N/A Applications: October 18, 2023 ; October 17, 2024	\$90,000/year in salary; \$50,000/year in other program-related expenses

Entrepreneurial Development Funding Opportunities

Empowering spin-offs is critical to biomedical innovation, the economy, and the NIA mission. REDI provides bio-entrepreneurship training to further enrich and diversify NIA training programs. **REDI-supported trainees acquire additional non-academic skills for success**, such as science communications; intellectual property; regulatory affairs; science policy; consulting; drug discovery, approval, and production; and the business of science, science education, and health care. **Participants from diverse backgrounds are particularly encouraged to apply.**

Visit: <https://www.nia.nih.gov/research/sbir/nia-research-and-entrepreneurial-development-immersion-redi>



Questions? Contact Joshua Hooks, Ph.D.

NIA Research and Entrepreneurial Development Immersion (REDI)

	FOAs	Due Dates	Budget Limits
SBIR	<u>RFA-AG-24-042</u> (REDI Entrepreneurial Small Business Transition Award; clinical trial optional) <i>Key Eligibility: Within 10 years of PhD, first time PI on R grant</i>	Letter of Intent: September 26, 2023 <i>Application: October 26, 2023</i>	Phase I \$500,000; Fast-Track \$2.5 million
STTR	<u>RFA-AG-24-043</u> (REDI Entrepreneurial Small Business Transition Award; clinical trial optional) <i>Key Eligibility: Within 10 years of PhD, first time PI on R grant</i>	Letter of Intent: September 26, 2023 <i>Application: October 26, 2023</i>	Phase I \$500,000; Fast-Track \$2.5 million

REDI SBIR/STTR



- A novel SBIR/STTR mechanism for which the PI must:
 - Be **within 10 years** of their terminal degree
 - Have not previously been a PI on a NIH small business or research grant.
 - Have a dedicated Entrepreneurial Mentor
 - Must include a **Career Development Plan**

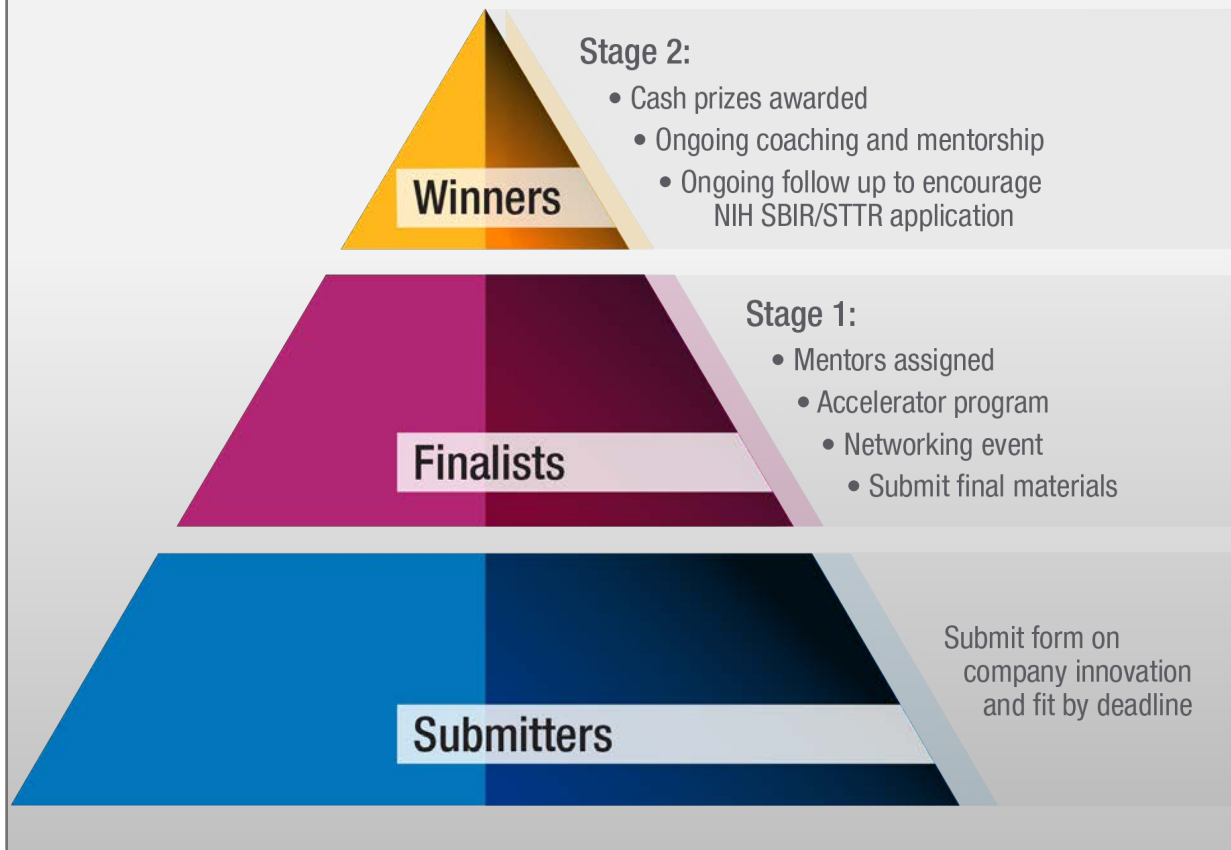
Visit: <https://www.nia.nih.gov/research/sbir/nia-research-and-entrepreneurial-development-immersion-redi>



NIA Startup Challenge and Accelerator *Fostering Entrepreneurial Diversity*

Addressing challenges faced by diverse innovators & innovations impacting health disparities

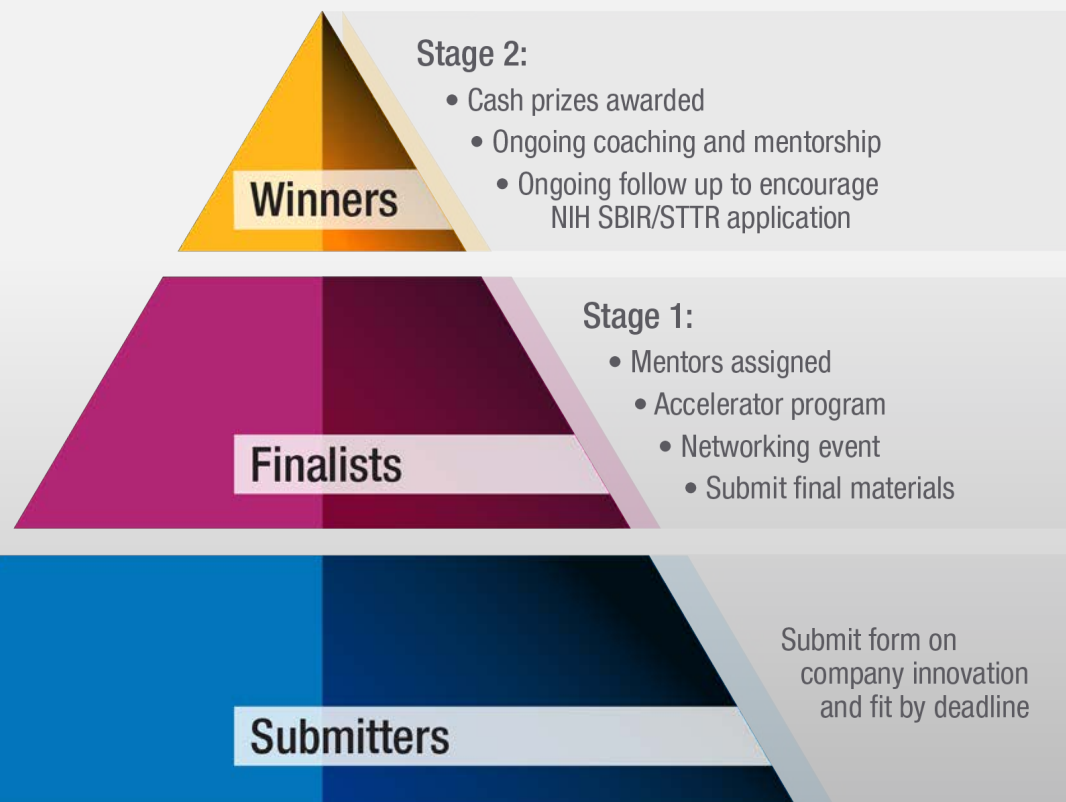
Challenge finalists participate in a **five-month entrepreneurial bootcamp**, receive mentorship, and compete for a cash prize



NIA Startup Challenge and Accelerator Fostering Entrepreneurial Diversity

Addressing challenges faced by diverse innovators & innovations impacting health disparities

Challenge finalists participate in a **five-month entrepreneurial bootcamp**, receive mentorship, and compete for a cash prize



**1-on-1 Mentoring and
Access to experienced networks**

In-depth entrepreneurial training

Topics including but not limited to:

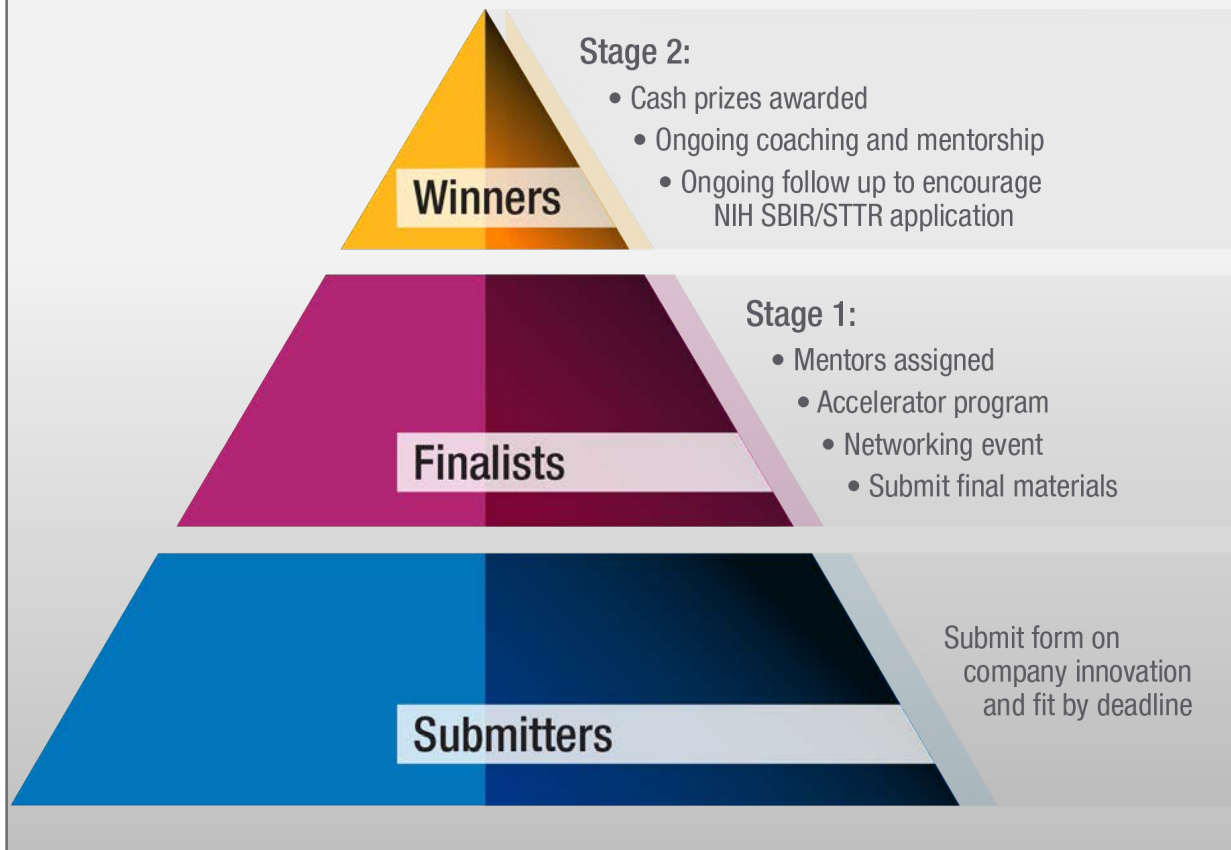
- NIH SBIR Funding
- Customer discovery
- Innovating for health equity
- Navigating entrepreneurship as a diverse founder
- Go to market strategy
- Intellectual property
- FDA regulatory strategy
- Branding and messaging
- Pro forma financials
- Valuation
- Investor discovery and due diligence



NIA Startup Challenge and Accelerator *Fostering Entrepreneurial Diversity*

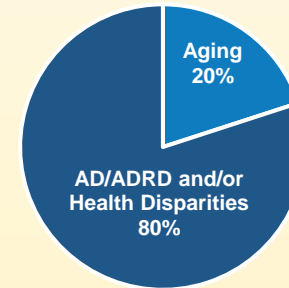
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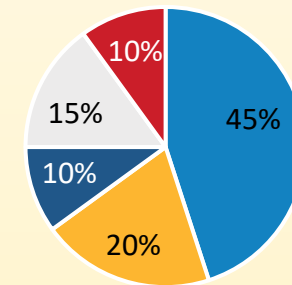


2022 Challenge Cohort:

Solution Focus



Solution Type



- Digital Health
- Therapeutics
- Research Tool
- Sensors & Monit. Tech
- Diagnostic



NIH Applicant Assistance Program

- Free application preparation **assistance** for 10 weeks
- Participating ICs: NIA, NCI, NHLBI, NINDS, NCCIH, NCATS, NIEHS and NINR

Goal:
Provide a mentor for applicants with great technology but little NIH experience and limited NIH experience in their network.

PROVIDED	NOT PROVIDED
Phase I preparation support and review	Grant writer
Specific Aims page review and advice	Development of research plan
Submission process coaching	Register small business for you Apply to NIH for you



NIH Applicant Assistance Program: Eligibility and Process

- Simple eligibility criteria:
 - ❖ Never received a small business grant award from NIH
 - OR**
 - ❖ Received an award over 10 years ago
- Interested in applicants who are currently underrepresented in the biosciences (not a requirement)
 - ❖ Women-owned small businesses
 - ❖ Minority-owned small businesses
 - ❖ Small businesses operating in an underrepresented (IDeA) state

AAP application portal:

<http://bit.ly/2020AAP>

- Answer a series of structured questions
- Upload supporting documents (e.g., abstract)
- Submit

Now accepting applications for January 5th deadline!

Submission Portal Closes:

Sept. 12th, 2023, 5:00 pm ET



We are a resource for all applicants and awardees. Please reach out to us to get started!

NIA Office of Strategic Extramural Programs (OSEP)



Todd Haim, Ph.D.
OSEP Director



Shoshana Kahana, Ph.D.
OSEP Deputy Director

Small Business Programs



Armineh Ghazarian, M.S.F.
Program Analyst



Rajesh Kumar, Ph.D.
Program Officer



Michael-David Kerns, Ph.D.
Program Officer



Joy Toliver, M.P.H.
Program Analyst



Joshua Hooks, Ph.D.
AAAS Science and
Technology Policy Fellow

Training & Career Development Programs



Maria Carranza, Ph.D.
Program Officer



Jamie Lahvic, Ph.D.
Program Officer

Cross-Functional Support



Chelsea Dinneny, B.A.
Program Analyst



Douglas Rojas, A.A.
Operations Coordinator (Contr.)

Any Questions?



Please reach out if you have any questions!

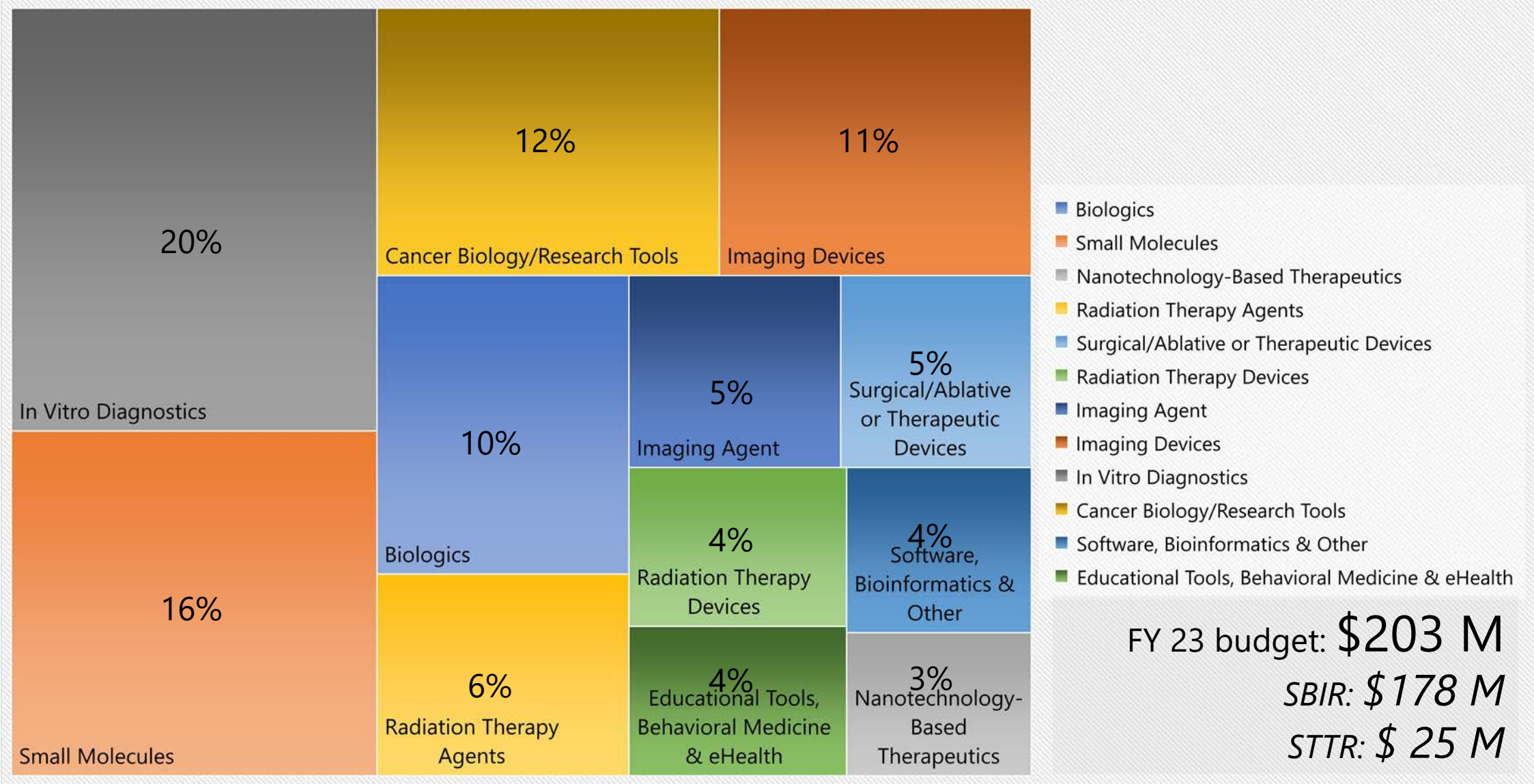
niasmallbusiness@mail.nih.gov



Saroj Regmi, Ph.D.

Program Director
SBIR Development Center
NCI

NCI SBIR-Funded Portfolio



THREE-PHASE PROGRAM



BUDGET LIMITS

	Hard Cap	Waiver Cap*
Phase I	\$295,924	NCI: \$400,000
Phase II	~\$1.97M	NCI: \$2.0M

* Waiver cap is institute specific. The waiver cap listed above is for NCI only.

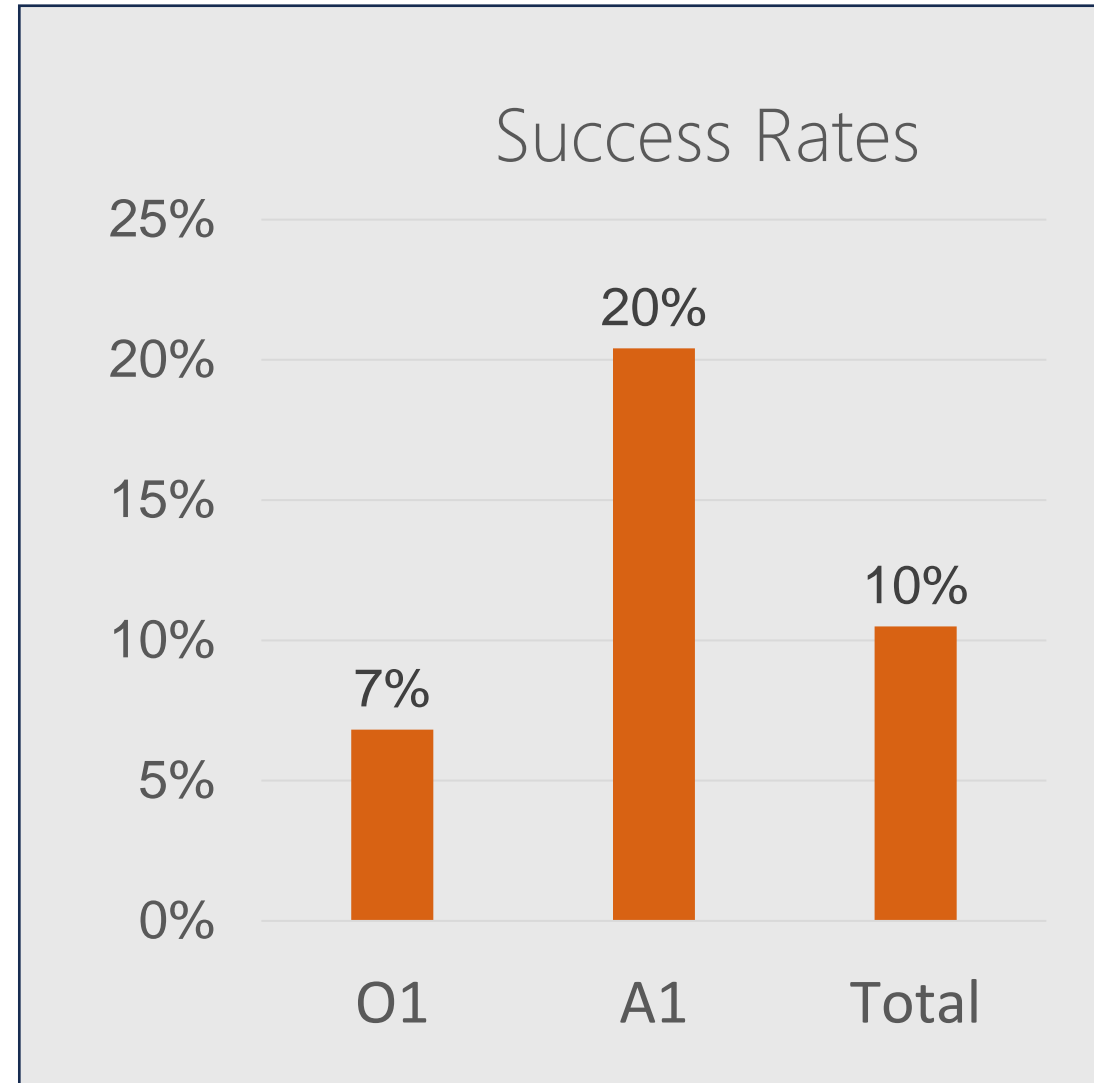
For the list of SBIR/STTR Waiver Topics for NCI, visit [Appendix A](#)

WAIVER TOPICS

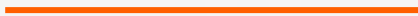
- Therapeutics (e.g. Small Molecules, Biologics, Radiomodulators, Cell-based Therapies and Drug Development- Related IT Tool and Algorithm Development)
- In Vitro and In Vivo Diagnostics (e.g. Companion Diagnostics, Prognostic Technologies, Treatment Monitoring and Diagnostic-Related IT Tool and Algorithm Development)
- Imaging Technologies (e.g. Agents, Devices, Software Tools, Algorithm Development, and Image-Guided Interventions)
- Devices for Cancer Therapy (e.g. Interventional Devices, Software Tools, Algorithm Development, Surgical, Radiation and Ablative Therapies)
- Agents for Cancer Prevention (e.g., Vaccines, but not “Technologies for Cancer Prevention”)
- Development of Low-Cost Technologies for Low-Resource Settings and Cancer Global Health
- Development of Digital Health Tools

FY21 GRANTS SUCCESS RATES

Grant Type (Phase I, Phase II, Fast-Track, Phase IIB, Direct-To-Phase II)	Number of Competing Applications	Number of Competing Awards
Original Submission (O1)	1056	72
Resubmission (A1)	392	80
Total (O1 + A1)	1448	152



FUNDING OPPORTUNITIES



FUNDING OPPORTUNITIES

TITLE SBIR FOA STTR FOA RECEIPT DATES

Omnibus Solicitation

PA-22-176 (General)
PA-22-177 (Clinical Trial)

PA-22-178 (General)
PA-22-179 (Clinical Trial)

Notice of Special Interest for Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings

NOT-CA-21-062

NOT-CA-21-062

Standard Receipt Dates
April 5;
September 5;
January 5

Notice of Special Interest (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

Notice of Special Interest: SBIR Technology Transfer

NOT-NS-22-017

Technology Development for Single-Molecule Protein Sequencing

PAR-21-247

No STTR

TBD

Small Business Transition Grant for Early Career Scientists

No SBIR

RFA-CA-23-035

TBD ~ Aug 2024

NCI SBIR Concept Award (Contract)

75N91023R00034

No STTR

TBD ~ Aug 2024

NCI SBIR Phase IIB Bridge

RFA-CA-23-034

No STTR

TBD ~ Aug 2024

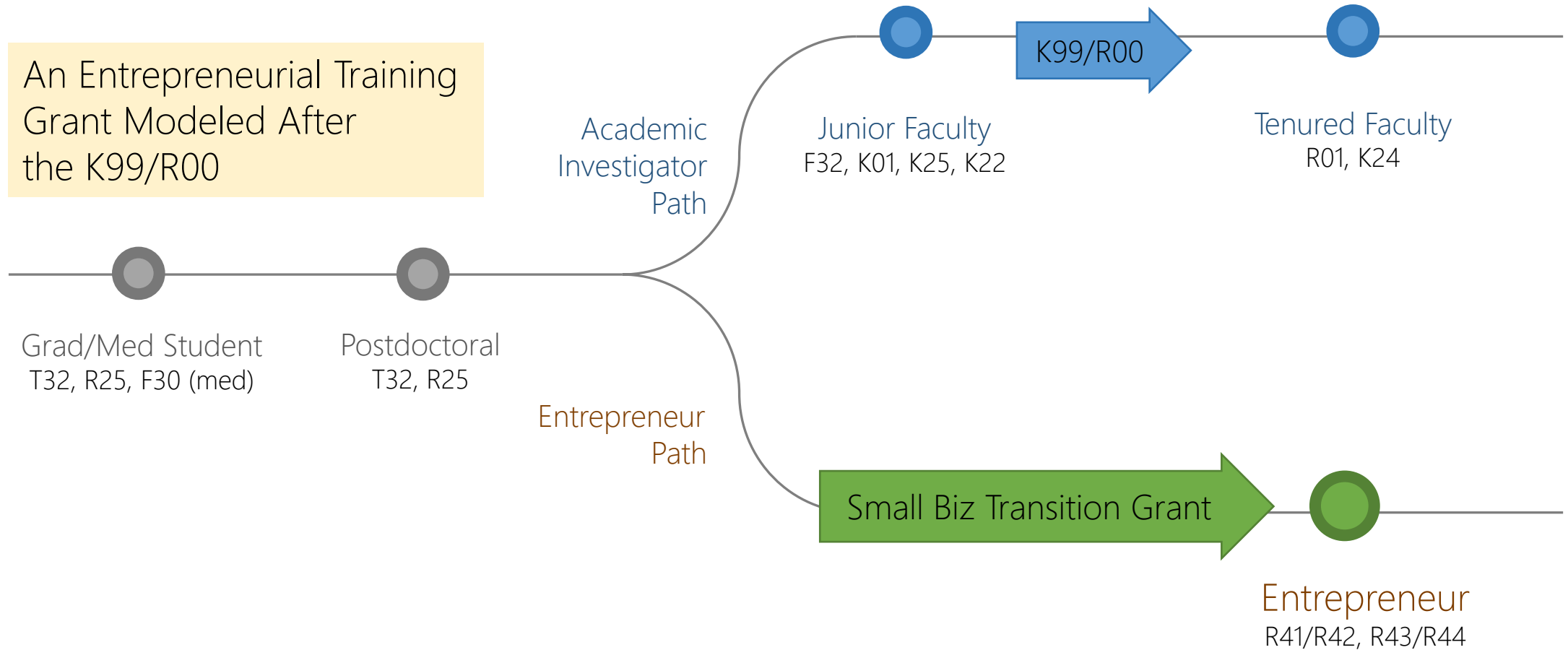
Contract Solicitation

Coming Soon

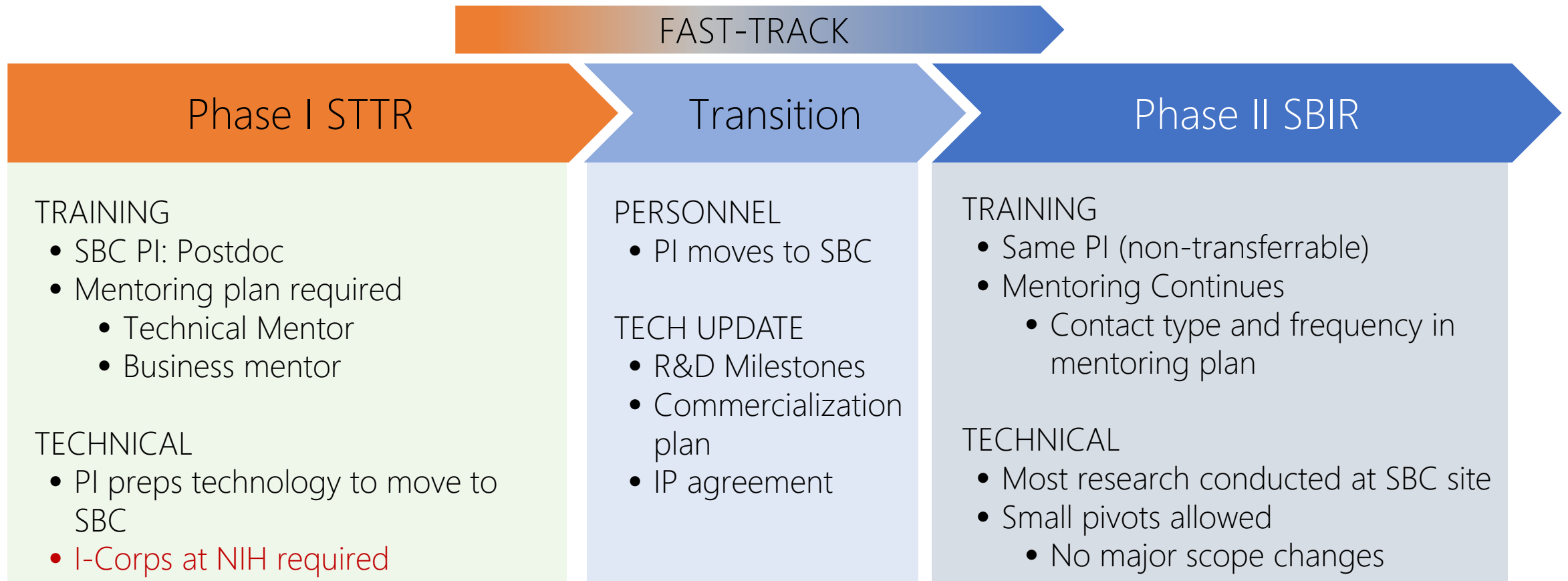
No STTR

TBD ~Oct./Nov. 2023

Small Business Transition Grant For Early Career Scientists



SMALL BUSINESS TRANSITION GRANT (SBTG): TRANSITIONING TO ENTREPRENEURSHIP



[Click here for more information about SBTG](#)

Next Receipt Date: TBD

CONCEPT AWARD



- Phase I SBIR Contract Funding (\$300K)
- Focus is on innovation
- Disruptive technologies to address rare and pediatric cancer
- Short applications (~20 pages vs. 50)
- Special review criteria with focus on innovation
- Fund experiments to de-risk early-stage technologies
- Make awards rapidly (within six months)
- Awardees are expected to enroll in the NIH I-Corps Program

Solicitation TBD

CONTRACT TOPICS

The FY24 SBIR Contract Solicitation topics are now available. See below for the 11 topics that will be included in this year's solicitation.

- Ultra-Fast Dose Rate (FLASH) Radiation
- Technologies for Detecting Tumor-Derived Cell Clusters
- Rapid and Affordable Point-of-Care HPV Diagnostics for Cervical Cancer Control
- Translation of Novel Cancer-Specific Imaging Agents and Techniques to Mediate Successful Image-Guided Cancer Interventions
- Microbiome-Based Tests for Cancer Research, Diagnosis, Prognosis, and/or Patient Management
- Organ-on-Chip for Preclinical and Translational Radiobiological Studies
- Point-of-Care Detection of Prostate Specific Antigen
- Cancer Prevention and Treatment Clinical Trials Tools for Recruitment and Retention of Diverse Populations
- Cloud-Based Multimodal Data Analysis Software for the Cancer Research Data Commons
- Evaluation Datasets as Medical Device Development Tools for Testing Cancer Technologies
- Automated Software for Point-of-Care Testing to Identify Cancer-Associated Malnutrition

PHASE IIB BRIDGE AWARD



- Provides up to \$4M in additional funding over 2-3 years
- Technology validation and clinical translation
- Open to Phase II awardees from *any Federal agency* with projects relevant to NCI mission
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners earlier in the development process
- Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., $\geq 1:1$ match)
- **Next Receipt Date TBD**

SUCCESS STORY: IMMUNOMEDICS



Trodelvy
(Sacituzumab Govitecan-hziy)
Antibody drug conjugate that is directed against Trop-2, a cell-surface protein expressed in many solid cancers.



2012

Immunomedics received SBIR award and used it to fund the first in-human trial of Trodelvy.



April, 2020

FDA approved Trodelvy for treatment of Triple Negative Breast Cancer.



September 2020

Gilead agreed to acquire Immunomedics for ~\$21 billion

Reach Out to a Program Director



Michael Weingarten, MA
Director
NCI SBIR Development Center

<https://sbir.cancer.gov/about/contact-staff>



Greg Evans, PhD
Lead Program Director
Cancer Biology, E-Health,
Epidemiology, Research Tools



Jonathan Franca-Koh, PhD, MBA
Lead Program Director
Cancer Biology, Biologics, Small
Molecules, Cell Based Therapies,
Phase IIb Bridge



Monique Pond, PhD
Lead Program Director
Biologics, Small Molecules,
Therapeutic Devices, Digital
Health, Regulatory Resources



Patricia Weber, DrPH
Program Director
Digital Health, Therapeutics,
Biologics, Resources



William Bozza, PhD
Program Director
Therapeutics, Biologics, Small
Molecules, Regulatory (CMC),
Concept Award, PLAN Webinar



Jian Lou, PhD
Program Director
In-Vitro Diagnostics, Theranostics,
early-stage drug development,
Bioinformatics, Investor Initiatives



Ming Zhao, PhD
Program Director
Cancer Diagnostics & Therapeutics, Cancer Control
& Prevention, Molecular Imaging, Bioinformatics,
Stem Cells



Saroj Regmi, PhD
Program Director
Therapeutics, Diagnostics, Imaging,
Digital Health, Investor Initiatives, Small
Business Transition Grant, I-Corps



Sarra Djemil, PhD
Program Director
Therapeutics &
Mentoring



Swamy Tripurani, PhD
Program Director
Therapeutics, Biologics, Small
Molecules, diagnostics, devices, and
Regulatory (CMC and Nonclinical))

ASSISTANCE and INITIATIVES



NCI SBIR ASSISTANCE



Application Assistance Program

I-Corps at NIH

NCI Investor Initiatives

NCI Peer Learning and Networking (PLAN) Webinar

NCI Resources for Commercialization Workshops

Executive Roundtable

Connecting Awardees to Regulatory Experts (CARE)

Industry Mentoring and Assistance Program (IMAP)

Women's Innovation Network(WIN)

<https://sbir.cancer.gov/resources>



Phase I

Grants

Contracts

Program for SBIR/STTR Phase I awardees (Grants + Contracts) to help:

- 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

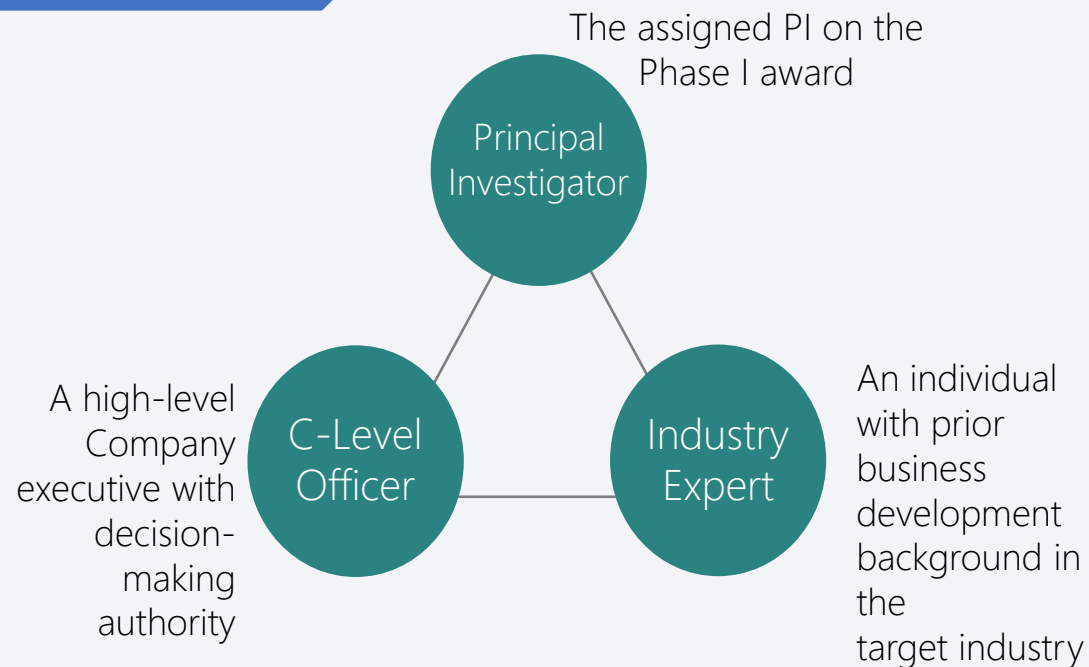
For more information, please see –
<https://seed.nih.gov/I-Corps-at-NIH>

I-Corps at NIH: Details

REQUIREMENT

Eligible SBIR/STTR grantees are required to assemble 3-member teams that will work collaboratively to complete the activities and assignments required by the I-Corps curriculum

THE I-CORPS TEAM



INSTRUCTORS

- Experienced, business-savvy instructors work closely with project teams to help them explore potential markets for their Federally funded innovations
- Instructors possess specific domain expertise in the major product areas that comprise the biomedical industry

AWARD

- \$55K to support entrepreneurial training, mentorship, and collaboration opportunities

ELIGIBILITY

- To be eligible, a company must have an ACTIVE Phase I SBIR or STTR grant from one of the 24 participating NIH and CDC Institutes and Centers
- The predicate Phase I grant must have project and budget timelines that are active from application date through end of I-Corps course syllabus

PLAN WEBINAR SERIES

Peer Learning and Networking (PLAN) Webinar Series



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.

Topics:

- How to Write a Good Specific Aims Page ✓ Video content available
- Implementing a Quality Management System (QMS) ✓ Video content available
- First Steps for Starting a Small Business ✓ Video content available
- Keys to a Successful IND Submission
- Small Business Transition Grant (SBTG)
- Connecting Awardees with Regulatory Experts (CARE) program

INVESTOR INITIATIVES PROGRAM OUTCOMES

- Phase I
- Phase II
- Phase IIB
- Grants
- Contracts



INVESTOR REVIEW //

Current and recent NCI awardees can apply (80-110 per year)

Reviewed by pharma and venture partners (e.g., Pfizer, J&J, GE, MPM Capital)

ALL applicants receive constructive feedback from investor reviewers



FUNDING SUPPORT TO PITCH //

NCI matches 25-30 companies with stage and technology appropriate events

Assists with presentation fees for one individual

NCI or Pharma managed company showcases



MENTORING & PITCH COACHING //

Selected companies receive coaching, give pitches at investor forums and conferences, and meet one-on-one with investor attendees

Industry mentoring



DIRECT INTRODUCTION TO INVESTORS //

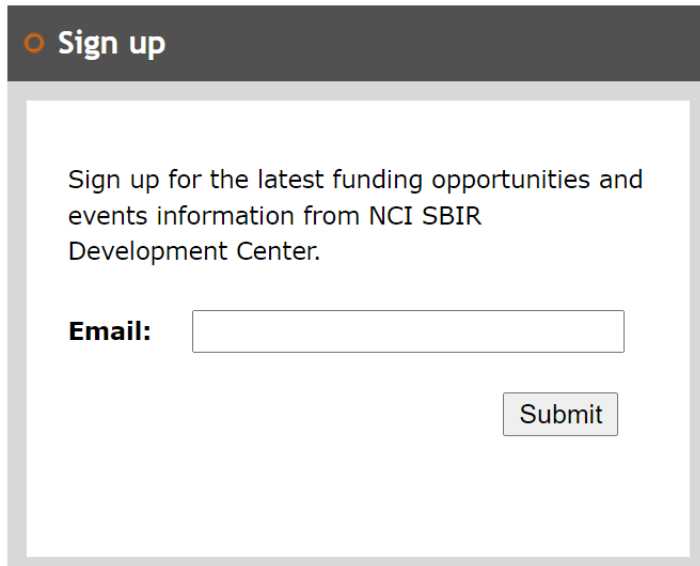
Develop a wide network of investor/strategic partners

Companies are profiled in an investor-oriented booklet shared via newsletters

Direct introductions to SBIR awardees in NCI SBIR portfolio

EVENTS

Learn about our funding opportunities and resources from NCI SBIR program directors!



The screenshot shows a sign-up form with a dark header containing the text "Sign up" with a small orange circle icon. Below the header, the text reads "Sign up for the latest funding opportunities and events information from NCI SBIR Development Center." There is an "Email:" label followed by a text input field. A "Submit" button is located at the bottom right of the form area.

- NCI SBIR Monthly Office Hour
 - 3rd Friday of each month
 - Registration sheet to become available soon.
 - A great opportunity to connect one-on-one with an NCI SBIR program director
 - Sign up and send your 1-page technology summary to Bryce Geiling (bryce.geiling@nih.gov).
- Upcoming events
 - Events are listed on NCI SBIR Events Page: <https://sbir.cancer.gov/newsevents/events>
 - Sign up for e-newsletter for the latest update: <https://sbir.cancer.gov/emailsignup>

THANK YOU

CONTACT INFO

NCI SBIR DEVELOPMENT CENTER

ncisbir@mail.nih.gov

240.276.5300



Moderated Q&A

ncats.nih.gov/smallbusiness

NCATS-SBIRSTTR@mail.nih.gov



A horizontal black bar containing meeting controls. From left to right: 'Audio Settings' with an upward arrow icon; 'Chat' with a speech bubble icon; 'Raise Hand' with a hand icon; 'Q&A' with a speech bubble icon; and 'Leave Meeting' in red text.

Translational Science and Research Areas of Interest

SBIR and STTR programs support NCATS' **mission to transform the translational science process** so that **new treatments and cures** for disease can be **delivered to patients more efficiently**.

TOPICS OF INTEREST

1. Preclinical Drug Discovery & Development
2. Biomedical, Clinical & Health Research Informatics
3. Clinical, Dissemination & Implementation Research

2024 DEADLINES:

January 5
April 5
September 5



THANK YOU

