March 17, 2021 | BHI VIRTUAL SBIR & OTHER NON-DILUTIVE FUNDING SOURCES WORKSHOP

FUNDING AND COMMERCIALIZATION RESOURCES FOR CANCER TECHNOLOGIES

REEMA RAILKAR

PROGRAM MANAGER
SBIR DEVELOPMENT CENTER
NATIONAL CANCER INSTITUTE





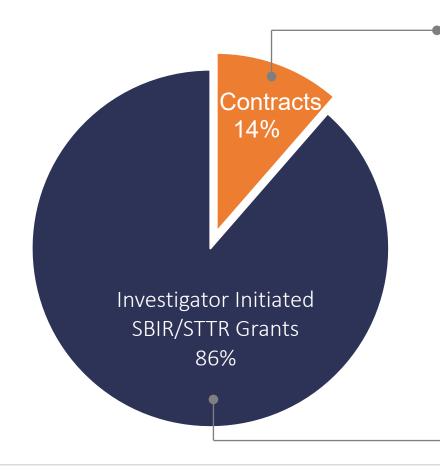
NCI SBIR SUPPORTS GRANTS & CONTRACTS

SBIR

Small Business
Innovation Research
(3.2%)

STTR

Small Business
Technology Transfer
(0.45%)



SBIR Contracts\$25M (FY2020)

- New topics once a year
- NIH-wide RFP
- R&D scope for topics defined by NCI

SBIR/STTR Grants

* \$150M (FY2020)

NCI SBIR CORE ACTIVITIES



CENTRAL OVERSIGHT

Administer all 400+ SBIR/STTR awards at the NCI



GUIDANCE

Help prepare for application, resubmission, & discuss funding options



OUTREACH

Attend conferences/workshops & visit organizations/universities to raise awareness of the program



FUNDING

Seed emerging technology areas through targeted grant & contract funding opportunities



NETWORKING

Maintain a network of investors and facilitate connections between portfolio companies & investors/strategic partners



TRAINING

Provide entrepreneurship training on key topics such as IP, regulatory strategy, & how to build a strong team



REACH OUT TO AN NCI SBIR PROGRAM DIRECTOR



Michael Weingarten, MA Director **NCI SBIR Development Center**



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



Deepa Narayanan, MS Lead Program Director Imaging, Clinical Trials, Radiation Therapy, Investor Initiatives



Kory Hallett, PhD Lead Program Director Monoclonal Antibodies, Immunotherapy, Biologics, and **Program Analysis**





Christie Canaria, PhD **Program Director** Cancer/Biological Imaging, Research Tools, Devices, I-Corps at NIH



Nancy Kamei, PharmD, MBA Program Director **Cancer Therapeutics**



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



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



Monique Pond, PhD **Program Director** Biologics, Research Tools and **Regulatory Resources**



Amir Rahbar, PhD, MBA **Program Director** In-Vitro Diagnostics, Biologics, Therapeutics. Proteomics



William Bozza, PhD **Program Director** Biologics, Protein Therapeutics, Regulatory (CMC)



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



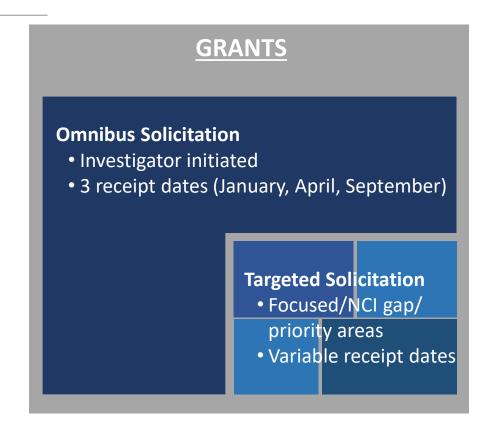
Ming Zhao, PhD **Program Director** Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells

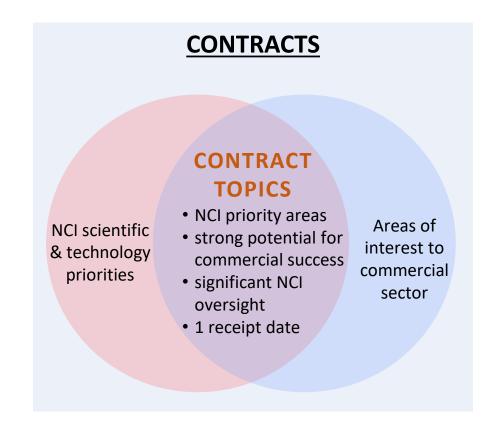
FUNDING OPPORTUNITIES

TITLE	SBIR FOA	STTR FOA	RECEIPT DATES	
Omnibus Solicitation	PA-20-260 (General) PA-20-262 (Clinical Trial)	PA-20-265 (General) PA-20-261 (Clinical Trial)	Standard Receipt Dates September 5; January 6; April 6	
SBIR Technology Transfer (technology transfer out of NIH intramural labs)	PA-18-705 (SBIR only)	No STTR		
Illuminating the Druggable Genome (IDG)	PA-19-034	PA-19-033		
Development of Highly Innovative Tools and Technology for Analysis of Single Cells	PA-20-047	PA-20-025		
Contract Solicitation	SBIR Only	No STTR	~ October 2021	
Phase IIB Bridge Award	RFA-CA-20-033	Same as SBIR	~ August 2021	
Small Business Transition Grant	RFA-CA-21-001		March 24, 2021	
NCI SBIR Concept Award	75N91020R00043	Contract (No STTR)	July 23, 2021	



R&D CONTRACTS



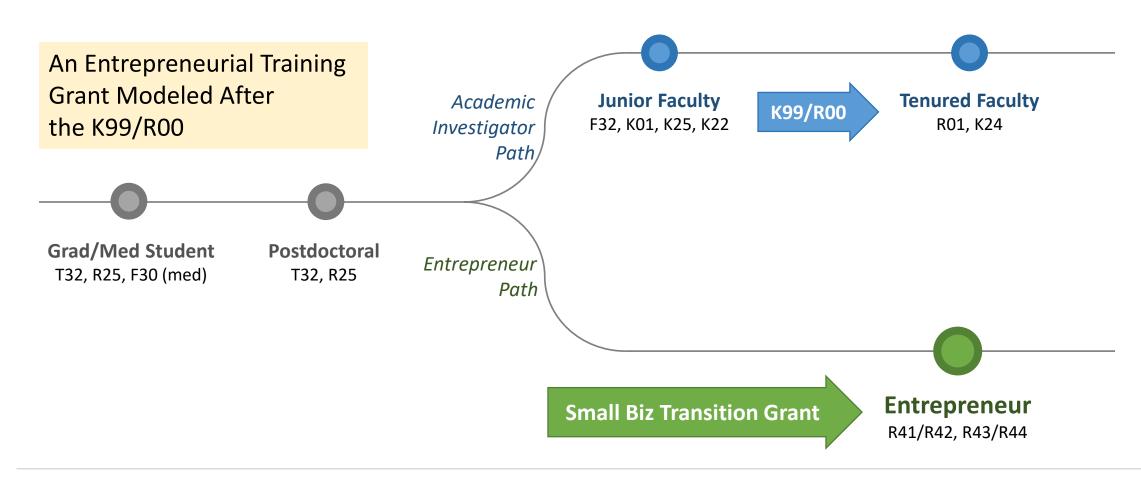


- Examples of previous R&D contracts from NCI are <u>here</u>.
- Next date for publication ~July 2021 for receipt date of ~October 2021.



SMALL BUSINESS TRANSTION GRANT

RFA-CA-21-001 - Small Business Transition Grant





CONCEPT: SMALL BUSINESS TRANSITION GRANT

FAST-TRACK

Phase I STTR

STTR

- Requires collaboration with university
- PI primary employment not stipulated (min.10% effort to project)
- \$400,000 / 12 months (NCI)

Phase II SBIR



- Permits collaboration with university
- PI primary employment MUST be with the SBC for the duration of the project period
- \$2M / 2yrs (NCI)



CONCEPT: SMALL BUSINESS TRANSITION GRANT

FAST-TRACK

Phase I STTR

Transition

Phase II SBIR

TRAINING

- SBC PI: Postdoc
- Mentoring plan required
 - Technical Mentor
 - Business mentor

TECHNICAL

- PI preps technology to move to SBC
- I-Corps at NIH required

PERSONNEL

PI moves to SBC

TECH UPDATE

- R&D Milestones
- Commercialization plan
- IP agreement

TRAINING

- Same PI (non-transferrable)
- Mentoring Continues
 - Contact type and frequency in mentoring plan

TECHNICAL

- Most research conducted at SBC site
- Small pivots allowed
 - No major scope changes



SMALL BIZ TRANSITION GRANT

RFA-CA-21-001

National Cancer Institute

Kory Hallett, PhD

Kory.Hallett@nih.gov

National Human Genome Research Institute

Heidi Sofia, MPH, PhD

Heidi.sofia@nih.gov

Eligibility

- Maximum 8-years from terminal degree
- Women and scientists from underrepresented groups encouraged

Mentoring (special review criteria)

- Technical mentor commitment: cannot mentor more than one entrepreneur simultaneously
- Business mentor: can utilize mentoring programs, but must identify a lead mentor
- Expect the mentors to commit to a <u>minimum</u> of 2 hours/week AND I-Corps at NIH (Phase I)

Technology Development is Critical

- Application MUST include milestones and go/no-go criteria for fast-track transition
- NCI is not guaranteeing training support to grantees whose technology fails



SMALL BUSINESS CONCEPT AWARD

WHAT IS THE CONCEPT AWARD?



- Looking for transformative technologies
- Phase I SBIR Contract Funding
- Technologies to address rare and pediatric cancer
- Fund experiments to obtain initial de-risking and proofof-concept data.
- \$300K FOR one year of funding
- Focus is on Innovation
- Improve cancer research, prevention, detection and care
- More information here.



UNIQUE FEATURES OF THE PROGRAM

RELEASED: NOVEMBER 20,2020 WHITE PAPER: March 26, 2021 PROPOSALS DUE: July 23, 2021

POINT OF CONTACT

Cherie Wells

SBIR Contract Analyst NCI Office of Acquisitions Phone: (240) 276-7255

E-mail: ncioasbir@mail.nih.gov

- De-risk disruptive innovation.
- Submission of White Paper to get Program input
- Short applications (15 pages v/s 50)
- Preliminary data are not required.
- Special Review Criteria
- Make awards rapidly (within six months).
- Single proposal due date.
- Leverage NIH I-Corps Program
- Followed by another Phase I, Direct to Phase II or Fast-Track

Program Solicitation



PHASE IIB BRIDGE AWARD

RFA-CA-20-033



- 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 <u>earlier in the development process</u>
- Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., ≥ 1:1 match)



NCI SBIR RESOURCES

INVESTOR INITATIVES PROGRAM

Connect companies to follow on funding Develop & maintain a network of investors and industry partners.



W Info

WEBINARS (PLAN)

Informational Webinars with content relevant to early-stage start-ups. Webinar content shared by peers.

I-CORPS @ NIH

Entrepreneurial Training Program Understand Value Proposition, Business Model and Stakeholders.



5\$

CARE (REGULATORY PROGRAM)

Connecting Awardees with Regulatory Experts at FDA Sharing FDA information with companies.



Educate and Connect companies with federal and non-federal commercialization Resources.



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MENTORING PROGRAM*

Industry & experienced mentor program for start-ups



Peer Mentoring Platform for C-Level Officers to share experience and expertise



TABA (NEEDS ASSESSMENT)

NIH Managed Technical and Business Assistance

External Contractor to help assess company's gap/need areas.







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

- Define the value proposition (e.g., clinical utility) <u>early</u> before spending millions saves time AND money
- Assess IP and regulatory risk before design and build
- Better understand core customers and the <u>specific</u> steps required for downstream commercialization
 - Teams are required to conduct 100 interviews over the period of 8 weeks
- Gather information essential to customer partnerships/ collaborations/ purchases before doing the science
- Identify financing vehicles before they are needed (helping to avoid the "Valley of Death")

For more information, please see – https://sbir.cancer.gov/icorps



Translational Resources to Expedite Commercialization Success(TRECS) Workshop

PANEL SESSIONS

- Learn to utilize various federal and non-federal resources to advance commercialization
- Panelists from a wide range of federal and private organizations

ONE-ON-ONE MEETINGS

- Opportunity to meet 1:1
 with panelists and NCI SBIR
 program directors
- Over 300 individual meetings planned

PEER LEARNING

- Opportunity to meet cancer experts from NCI
- Opportunity to network with peers from other SBCs.



INVESTOR INITIATIVES







- **CONTACT NCI SBIR PROGRAM BEFORE** YOU APPLY.
- SEND US YOUR SPECIFIC AIMS PAGE.

Web: https://sbir.cancer.gov Email: ncisbir@mail.nih.gov

Twitter: @NCISBIR

LinkedIn: http://bit.ly/ncisbirlinkedin

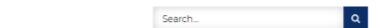
SBIR DEVELOPMENT CENTER













NCI Funding during the COVID-19 Public Health Emergency

Due to the potential impact of the declared public health emergency caused by COVID-19, the NIH has issued multiple quide notices, incluing notice on late applications. If your business is affected by COVID-19, check the list of available measures on our Notices Page.

For updates on NCI extramural funding activities, please check NCI Director Dr. Norman E. Sharpless' post on the NCI Bottom Line blog.

What are the NCI SBIR & STTR Programs?

The SBIR & STTR Programs are one of the largest sources of early stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities.

Learn more about the programs >

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o Sign up					
events in	or the latest funding opportunities and formation from NCI SBIR nent Center.				
Email:					
	Submit				

Latest Announcements

New Supplement for Technologies Adapted for COVID-19

The NCI SBIR Development Center is issuing a Notice of Special Interest (NOSI) to highlight the urgent need for the development of prophylactic, therapeutic and diagnostic for

THANK YOU

CONTACT INFO

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