NCI SBIR/STTR PARs

Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings (R43/44 & R41/42 - Clinical Trial Optional)

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Goals

- The two FOAs encourages SBIR/STTR grant applications from small business concerns (SBCs) proposing commercially-directed research for the development of cancer prevention, diagnosis, or treatment technologies to improve cancer outcomes in **low- and middle-income countries (LMICs), and low-resource settings in the US**.
- Specifically, the FOAs encourage grant applications from SBCs to **develop or adapt, apply, and validate** existing or emerging technologies into user-friendly products for cancer prevention, diagnosis, or treatment in low-resource settings.
- The technologies may include, but are **not limited** to tools for vaccine dissemination/delivery, imaging, in vitro diagnosis, or treatment of pre-cancerous (pre-neoplastic) or cancerous lesions that are preventable or treatable within low-resource settings.
- Strong emphasis is placed on technologies that **directly provide or immediately lead to treatment options available in the local health system**.
- Projects funded by the two FOAs **may include patient enrollment in foreign countries**. It should be noted that applicants are required to include a statement in their applications on why these resources are not available in the US if a portion of the work is performed outside of the US.
- Products addressing **cancers of the cervix, colon/rectum, esophagus, and oral cavity** are particularly encouraged for this FOA. However, applications **may address any single cancer type**.

PAR-18-801: https://grants.nih.gov/grants/guide/pa-files/PAR-18-801.html (SBIR: R43/44)
PAR-18-802: https://grants.nih.gov/grants/guide/pa-files/PAR-18-802.html (STTR: R41/42)

SBIR ELIGIBILITY

- ✓ Applicant must be a Small Business Concern (SBC)
- ✓ Organized for-profit U.S. business
- ✓ 500 or fewer employees, including affiliates
- ✓ > 50% U.S.- owned by individuals and independently operated

Award ALWAYS made to the small business

OR

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

OR (*SBIR ONLY*)

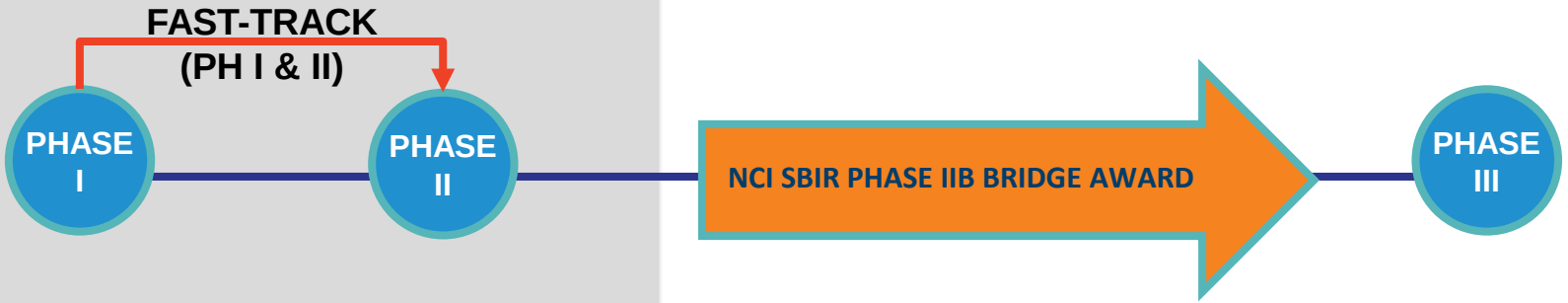
> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

STTR ELIGIBILITY

- Applicant is a Small Business Concern (SBC)
- Organized for-profit U.S. business
- Formal cooperative R&D effort
  - Minimum 40% by small business
  - Minimum 30% by US research institution
- US Research Institution: college or university; non-profit research organization; Federally-Funded R&D Center (FFRDC)
- Principal Investigator's primary employment may be with either the SBC or the research institution
- SBC must have right to IP to carry out follow-on R&D and commercialization

Award ALWAYS made to the small business

First-time applicants may submit a Phase I or Fast-Track application



- Proof-of-Concept
- **Up to $300,000**
- **Up to 12 months**

- Research & Development
- Commercialization plan required
- **Up to $2M**
- **Up to 2 years**

- Technology validation & clinical translation
- Follow-on funding for SBIR Phase II awardees from any federal agencies
- Expectation that applicants will secure substantial 3rd party investor funds
- **$4M over 3 years**

- Commercialization stage
- Use of non-SBIR/STTR funds

Key Dates

- **Posted Date: May 24, 2018**
- **Open Date (Earliest Submission Date): August 5, 2018**
- **Letter of Intent Due Date(s): 30 days prior to the application due date**
- **Application Due Date(s): September 5, 2018, January 5, 2019, April 5, 2019**
  Standard dates apply , by 5:00 PM local time of applicant organization
- **Expiration Date: January 6, 2021**
- **Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date**

Technology areas of interest include, but are not limited to, the following

- Machine learning algorithms to identify precancer and cancer in optical images captured with simple medical devices (e.g., smart phone)
- Machine learning approaches to enhance POC imaging, telemedicine, or digital pathology
- Software tools for cancer prevention, such as tools for vaccine dissemination, or tools to improve vaccine supply chains
- Delivery technologies to improve reliability, effectiveness, and/or safety of vaccines at the point of use (e.g., needle-free delivery methods, intradermal delivery that could reduce the quantity of vaccine required for an effective dose, or oral delivery)
- In vitro diagnostic assays such as Point-of-Care analytical tools for blood, saliva, or urine (e.g. lab-on-a-chip biosensors that allow remote performance of chemical and/or biological assays outside of a laboratory environment)
- Portable imaging devices for cancer diagnosis based for examples on optical imaging, spectroscopy, or ultrasound
- Devices for cancer treatment such as tools that may facilitate standard minimally invasive cancer treatment modalities, tools for cryotherapy, radiofrequency ablation, laser therapy, low-power-density sonication, high-intensity focused ultrasound or photodynamic therapy in a remote setting
- Devices to aid in delivery of cancer drugs
- Devices for treatment monitoring
- Tools for information and communications technologies to enhance cancer data collection, sharing, or analysis

Technologies that are generally not appropriate for this FOA include the following

- Devices that involve highly invasive interventions
- Devices that require extensive user training before they can be used
- Tools or devices that are exclusively focused on telemedicine
- Drug screening
- Companion diagnostics for high-cost drugs that are not affordable in low-resource settings

General Technology Characteristics and Attributes

- Highly portable
- Operable in locations with limited or no medical infrastructure, electricity, landline telephone communication, internet, refrigeration, or central water supply
- Connectable to the Internet as an option
- Low-cost
- Simple to operate by locally trained healthcare staff with minimal training

Investigator-Initiated Grants

Omnibus Solicitations (Phase I, Phase II, FastTrack)

- PA-18-573 & PA-18-574 (SBIR)
- PA-18-575 & PA-18-576 (STTR)

We encourage applications for any topic within the NIH mission

Due **September 5**, January 5, April 5

R&D Contract Funding Opportunity

- PHS 2019-1: HHS Small Business Innovation Research (SBIR) Program Contract Solicitation
- ONE application receipt date per year:
  - Published July 18, 2018

Receipt Date: October 22, 2018, 5:00 PM EDT

- RFP and Program Solicitation can be found at:
  - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-209.html
  - https://sbir.nih.gov/sites/default/files/PHS2019-1.pdf
  - More info about NCI's topic areas:
  - http://sbir.cancer.gov/funding/contracts/

FY19 NCI CONTRACT TOPICS

NIH/NCI 382 Integrated Subcellular Microscopy and 'Omics in Cancer Cell	**NIH/NCI 390** Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators
NIH/NCI 383 Smart, Multi-Core Biopsy Needle	**NIH/NCI 391** Drugs or Devices to Exploit the Immune Response Generated by Radiation Therapy
NIH/NCI 384 Digital Healthcare Platform to Reduce Financial Hardship for Cancer Patients	**NIH/NCI 392** Clinical Trials of Systemic Targeted Radionuclide Therapies (**FAST TRACK ONLY**)
NIH/NCI 385 Leveraging Connected Health Technologies to Address and Improve Health Outcomes of Long- Term Cancer Survivors	**NIH/NCI 393** Sensing Tools to Measure Biological Response to Radiotherapy
NIH/NCI 386 Novel Approaches for Local Delivery of Chemopreventive Agents	**NIH/NCI 394** Combinatory Treatment Modalities Utilizing Radiation to Locally Activate or Release Systemically Delivered Therapeutics
NIH/NCI 387 Multiplexed Preclinical Tools for Longitudinal Characterization of Immunological Status in Tumor and Its Microenvironment	**NIH/NCI 395** Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia
NIH/NCI 388 In vitro Diagnostic for the Liver Flukes Opisthorchis viverrini and Clonorchis sinensis	**NIH/NCI 396** Imaging for Cancer Immunotherapies
NIH/NCI 389 Development of Artificial Intelligence (AI) Tools to Understand and Duplicate Experts' Radiation Therapy Planning for Prostate Cancer	

NIH/NCI 396 - Imaging for Cancer Immunotherapies

Fast Track	# of anticipated awards	Budget (max)	
Accepted	3 - 4	Phase I - $300K for 9 months	Phase II - $2M for 2 years

Goal:
The goals of the solicitation are to develop a cancer imaging technology to identify patients who are likely to respond to cancer immunotherapies, evaluate the efficacy and potential toxicities of the treatment, and/or monitor cancer patients' prognosis. The imaging modality could be one of the following, but is not limited to: ultrasound imaging, optical imaging, photoacoustic imaging, PET, SPECT, MRI or combination of multiple modalities. Molecular markers of interest could include but are not limited to: cell surface receptors, immune or associated non-immune cells, cellular infiltrates, enzymes, metabolites or metabolic states, DNAs, RNAs, or epigenetic modifications. The technology development should be platform driven.

Phase I Activities and Deliverables include:
Phase I activities should generate scientific data confirming the clinical potential of the proposed imaging for cancer immunotherapies. The Phase I research plan must contain specific, quantifiable, and testable feasibility milestones.

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THE END