NCI SBIR/STTR PARs

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

Ming Zhao, PhD
NCI SBIR Development Center
July 24, 2018
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.

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

 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

Award ALWAYS made to the small business
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
First-time applicants may submit a Phase I or Fast-Track application.

**FAST-TRACK (PH I & II)**

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

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

**NCI SBIR PHASE IIB BRIDGE AWARD**

- 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

**PHASE III**

- 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:
- More info about NCI’s topic areas:
  - http://sbir.cancer.gov/funding/contracts/
<table>
<thead>
<tr>
<th>NIH/NCI 382</th>
<th>NIH/NCI 390</th>
<th>Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators</th>
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<tr>
<td>Integrated Subcellular Microscopy and ‘Omics in Cancer Cell</td>
<td>NIH/NCI 391</td>
<td>Drugs or Devices to Exploit the Immune Response Generated by Radiation Therapy</td>
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<td>NIH/NCI 383</td>
<td>NIH/NCI 392</td>
<td>Clinical Trials of Systemic Targeted Radionuclide Therapies (FAST TRACK ONLY)</td>
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<td>Smart, Multi-Core Biopsy Needle</td>
<td>NIH/NCI 393</td>
<td>Sensing Tools to Measure Biological Response to Radiotherapy</td>
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<td>Digital Healthcare Platform to Reduce Financial Hardship for Cancer Patients</td>
<td>NIH/NCI 394</td>
<td>Combinatory Treatment Modalities Utilizing Radiation to Locally Activate or Release Systemically Delivered Therapeutics</td>
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<td>Leveraging Connected Health Technologies to Address and Improve Health Outcomes of Long-Term Cancer Survivors</td>
<td>NIH/NCI 395</td>
<td>Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia</td>
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<td>NIH/NCI 386</td>
<td>NIH/NCI 396</td>
<td>Imaging for Cancer Immunotherapies</td>
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<td>Novel Approaches for Local Delivery of Chemopreventive Agents</td>
<td>Development of Artificial Intelligence (AI) Tools to Understand and Duplicate Experts’ Radiation Therapy Planning for Prostate Cancer</td>
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<tr>
<td>NIH/NCI 387</td>
<td>NIH/NCI 397</td>
<td>Sensing Tools to Measure Biological Response to Radiotherapy</td>
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<td>Multiplexed Preclinical Tools for Longitudinal Characterization of Immunological Status in Tumor and Its Microenvironment</td>
<td>NIH/NCI 398</td>
<td>Combinatory Treatment Modalities Utilizing Radiation to Locally Activate or Release Systemically Delivered Therapeutics</td>
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<td>NIH/NCI 388</td>
<td>NIH/NCI 399</td>
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<td>In vitro Diagnostic for the Liver Flukes Opisthorchis viverrini and Clonorchis sinensis</td>
<td>NIH/NCI 400</td>
<td>Imaging for Cancer Immunotherapies</td>
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<tr>
<td>NIH/NCI 389</td>
<td>NIH/NCI 401</td>
<td>Development of Artificial Intelligence (AI) Tools to Understand and Duplicate Experts’ Radiation Therapy Planning for Prostate Cancer</td>
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**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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<tr>
<th>Fast Track</th>
<th># of anticipated awards</th>
<th>Budget (max)</th>
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<tbody>
<tr>
<td>Accepted</td>
<td>3 - 4</td>
<td>Phase I - $300K for 9 months</td>
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THE END