MARCH 21-22, 2023 | NCI BSA MEETING

FY2024 SBIR CONTRACT TOPICS

Monique Pond, PhD

Team Lead & Program Director SBIR Development Center National Cancer Institute



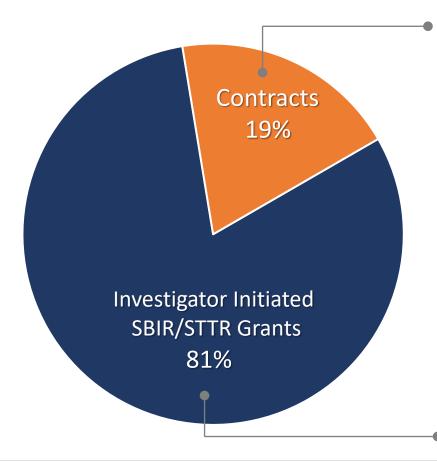
NCI SBIR SUPPORTS GRANTS & CONTRACTS

SBIR

Small Business
Innovation Research
(3.2%)

STTR

Small Business
Technology Transfer
(0.45%)



SBIR Contracts~\$37M (FY2022)

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

SBIR/STTR Grants

* ~\$155M (FY2022)

WHY DOES NCI SBIR FUND R&D CONTRACTS?









Address Specific Cancer Community Needs

Stimulate Commercialization in Emerging Areas Support Products in Challenging, High-Need Areas

Direct Funding to
Underrepresented
Areas in Our Portfolio

Example:

<u>De-Identification Software</u>
 <u>Tools and Pipelines for</u>
 <u>Cancer Imaging Research</u>

Example:

Ultra-fast Dose Rate
 (FLASH) Radiation
 Detectors and Safety
 Systems

Example:

 Advanced Manufacturing to Speed Availability of Emerging Autologous Cellbased Therapies

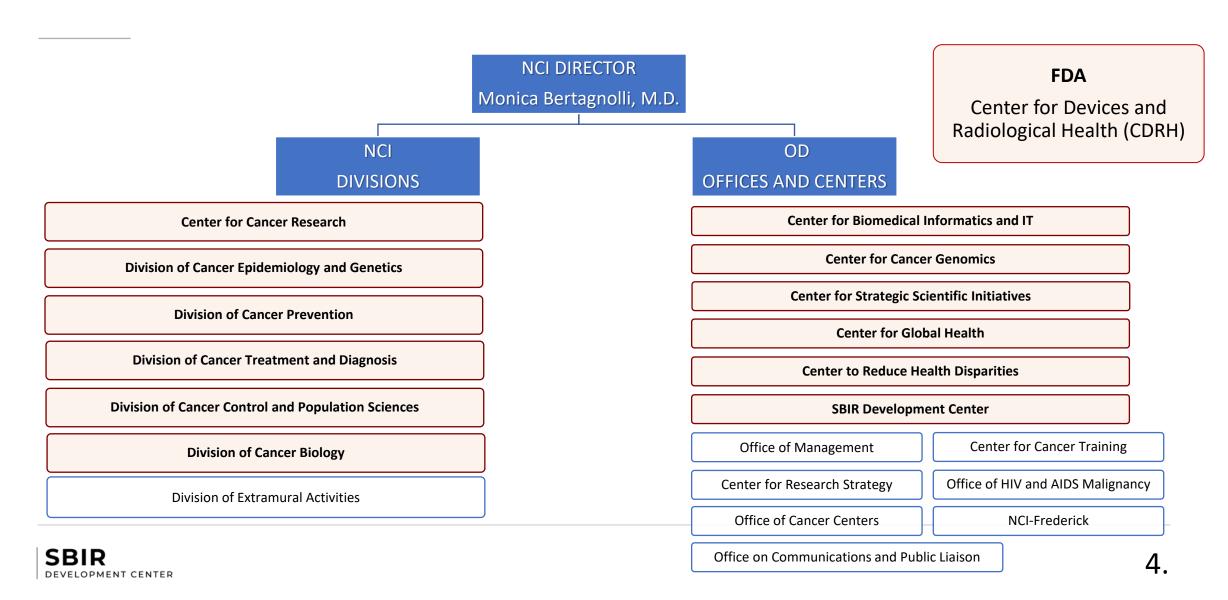
Example:

<u>Digital Tools to Improve</u>
 <u>Health Outcomes in</u>

 <u>Pediatric Cancer Survivors</u>



HOW DOES NCI SBIR DEVELOP CONTRACT TOPICS?



CONTRACT TOPIC SELECTION PROCESS - FY2024

November 2022
Receive Topic Solicitations

January 2023
Mail Ballot to SPL

March 2023 Present Topics to BSA July/August 2023 Topics Published

October 2022 Send Call to Divisions December 2022 Setup/Conduct TAG Reviews March 2023
Present Topics to ICC

May 2023 Final Topics to NIH SEED Office October 2023 Contract Proposal Receipt

18 Concept Ideas

NCI Technology Priorities

Commercial Potential

Portfolio Gaps

Technology Advisory Groups

- 1. Therapeutics, Clinical Diagnostics, and Molecular Analysis Techniques
- 2. Radiation Therapy, Medical Devices, and Information Technology

11 Topics	Therapeutics	Medical Devices	Clinical Diagnostics and Molecular Analysis	Information Technology and Bioinformatics
	0	1	6	4



MEDICAL DEVICES

Topic Title	Overall Goal
Ultra-Fast Dose Rate (FLASH) Radiation Detectors and Safety Systems for Cancer Treatment • Division of Cancer Treatment and Diagnosis	Advance the development of devices for evaluating FLASH radiation therapy and translating it into the clinic. This contract topic focuses on ultra-fast radiation dose detector and safety-related beam delivery components. # This topic is a re-issue
	Page 6



CLINICAL DIAGNOSTICS & MOLECULAR ANALYSIS

Topic Title

Technologies for Detecting Tumor- Derived Cell Clusters

- Division of Cancer Treatment and Diagnosis
- Center for Strategic Scientific Initiatives
- Division of Cancer Control and Population Sciences

Overall Goal

Support the development of *in vitro* technologies that can enumerate and identify cell types in tumor-derived cell clusters, with or without enrichment, to better understand the biology and role of different cells in cancer metastasis.

Moonshot Rec. (J) development of new enabling cancer technologies including molecular analysis technologies

Page 7

Rapid and Affordable Point-of-Care HPV Diagnostics for Cervical Cancer Control

- Center for Global Health
- Division of Cancer Prevention
- SBIR Development Center

Advance the development of new alternatives for HPV testing to the market that are both in a form factor and at a price point that will enable self-testing programs to be established globally.

Moonshot Rec. (G) expand use of proven cancer prevention and early detection strategies
This topic is a re-issue

CLINICAL DIAGNOSTICS & MOLECULAR ANALYSIS

Topic Title

Translation of Novel Cancer-Specific Imaging Agents and Techniques to Mediate Successful Image-Guided Cancer Interventions

- Division of Cancer Treatment and Diagnosis
- SBIR Development Center

Overall Goal

Support the translation of novel agents and/or techniques for sensitive cancer detection in human subjects. Ideally this would translate existing pre-clinical successes with activatable diagnostic probes to clinical tools that can detect small tumor cell clusters (~1mm³ in volume) via imaging.

Moonshot Rec. (J) development of new enabling cancer technologies including molecular analysis technologies # This topic is a re-issue

Page 9

Microbiome-Based Tests for Cancer Research, Diagnosis, Prognosis, and/or Patient Management

- Division of Cancer Biology
- Division of Cancer Control and Population Sciences
- SBIR Development Center

Support the development of innovative tests for early cancer detection/diagnosis, prognosis, and/or treatment assignment to be used in research. These advances could lead to the development of microbiome-based CLIA tests (laboratory-developed tests) and FDA-approved diagnostic or companion diagnostic tests.

Moonshot Rec. (J) development of new enabling cancer technologies to characterize tumors

CLINICAL DIAGNOSTICS & MOLECULAR ANALYSIS

Topic Title	Overall Goal
Organ-on-Chip for Preclinical and Translational Radiological Studies Division of Cancer Treatment and Diagnosis SBIR Development Center	Support the development and validation of organ-on-chip devices for research and preclinical applications in studies with radiation and drug radiation combinations. Moonshot Rec. (J) development of new enabling cancer technologies including 3D organ-like cultures Page 11
Point-of-Care Detection of Prostate Specific Antigen Division of Cancer Prevention SBIR Development Center	Advance the development of a home PSA test at an appropriate price point. This contract topic supports technologies designed for ease of use at home and using a finger stick to obtain a blood sample. Moonshot Rec. (G) expand use of proven cancer prevention and early detection strategies



INFORMATION TECHNOLOGY & BIOINFORMATICS

Topic Title	Overall Goal
Cancer Prevention and Treatment Clinical Trials Tools for Recruitment and Retention of Diverse Populations • Division of Cancer Prevention • SBIR Development Center	Support the development of a digital platform that provides PCPs with validated cancer risk assessment tools, cancer prevention guidelines, and clinical recommendations based on a patient's risk factors to discuss with their patients. Moonshot Rec. (A) establish a network for direct patient engagement # This topic is a re-issue
Cloud-Based Multimodal Data Analysis Software for the Cancer Research Data Commons • Center for Biomedical Informatics and IT	Advance the evolution of cloud-based multimodal informatics tools to integrate with the CRDC for broader user community engagement. Moonshot Rec. (D) build a national cancer data ecosystem # This topic is a re-issue



INFORMATION TECHNOLOGY & BIOINFORMATICS

Topic Title	Overall Goal
Evaluation Datasets as Medical Device Development Tools for Testing Cancer Technologies Food and Drug Administration Center for Biomedical Informatics and IT SBIR Development Center	Stimulate the participation of small businesses in the FDA's Medical Device Development Tool (MDDT) program to develop datasets that can be used to assess medical devices in oncology settings. # This topic is a re-issue
Automated Software for Point-of-Care Testing to Identify Cancer-Associated Malnutrition Division of Cancer Prevention SBIR Development Center	Facilitate the commercial development of novel automated point-of-care nutrition screeners that combine first-line questionnaires with automated segmentation from diagnostic imaging (e.g., from repurposed CT images) to detect malnutrition risk early and repeatedly during cancer care and in cancer populations with higher prevalence of malnutrition.



SUCCESS STORIES



RADTOX – cfDNA TEST

Monitoring radiation therapy toxicity in cancer patients



INSIGHT-RET SCREEN

CLIA-validated assay that detects oncogenic RET (rearranged during transfection) expression in non-small cell lung cancer (NSCLC) patients



DIGITAL CLINICAL TRIAL PLATFORM

Global Screening & Enrollment, Virtual Consent, Telemedicine & ePRO, and Electronic Clinical Outcome Assessment



cynvenio

CLEARID® BREAST CANCER TEST

Identifies circulating tumor cell burden and detects emerging genetic alterations that are associated with therapy resistance





BRACHYTHERAPY DEVICE

510(K) cleared device used in clinics for lung, pancreas, colorectal, sarcoma, and head & neck cancers





THANK YOU

NCI SBIR DEVELOPMENT CENTER ncisbir@mail.nih.gov 240.276.5300



