JUNE 12, 2024 | NCI BSA MEETING

# FY2025 SBIR CONTRACT TOPICS

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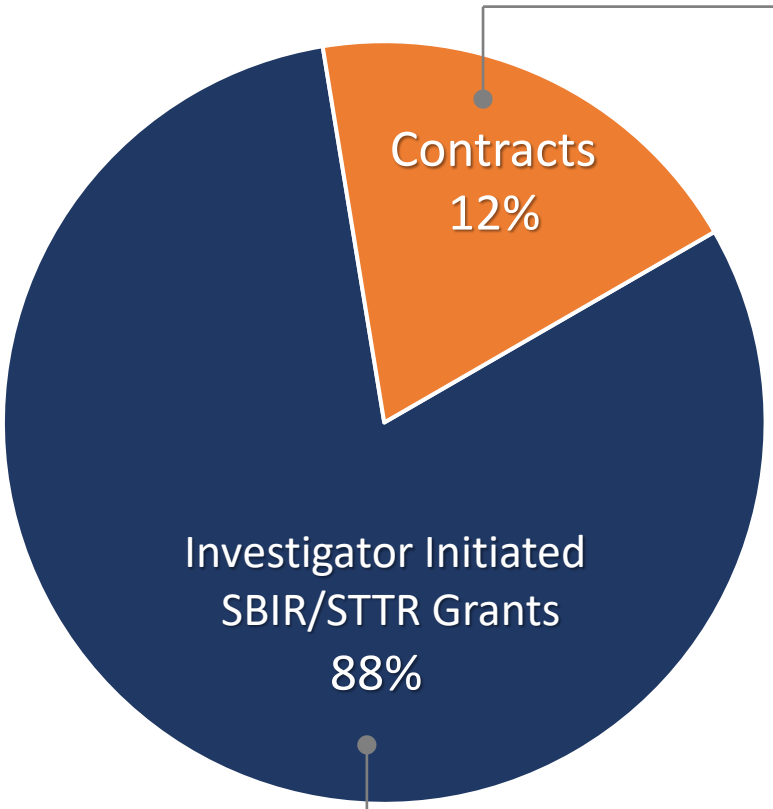
# NCI SBIR SUPPORTS GRANTS & CONTRACTS

**SBIR**
Small Business Innovation Research (**3.2%**)

**STTR**
Small Business Technology Transfer (**0.45%**)




## SBIR Contracts

**~$24M (FY2023)**

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

## SBIR/STTR Grants

**~$179M (FY2023)**



*Small business awards do not affect the RPG pool*

# WHY DOES NCI SBIR FUND R&D CONTRACTS?

## Address Specific Cancer Community Needs

Example:

- De-Identification Software Tools and Pipelines for Cancer Imaging Research

## Stimulate Commercialization in Emerging Areas

Example:

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

## Support Products in Challenging, High-Need Areas

Example:

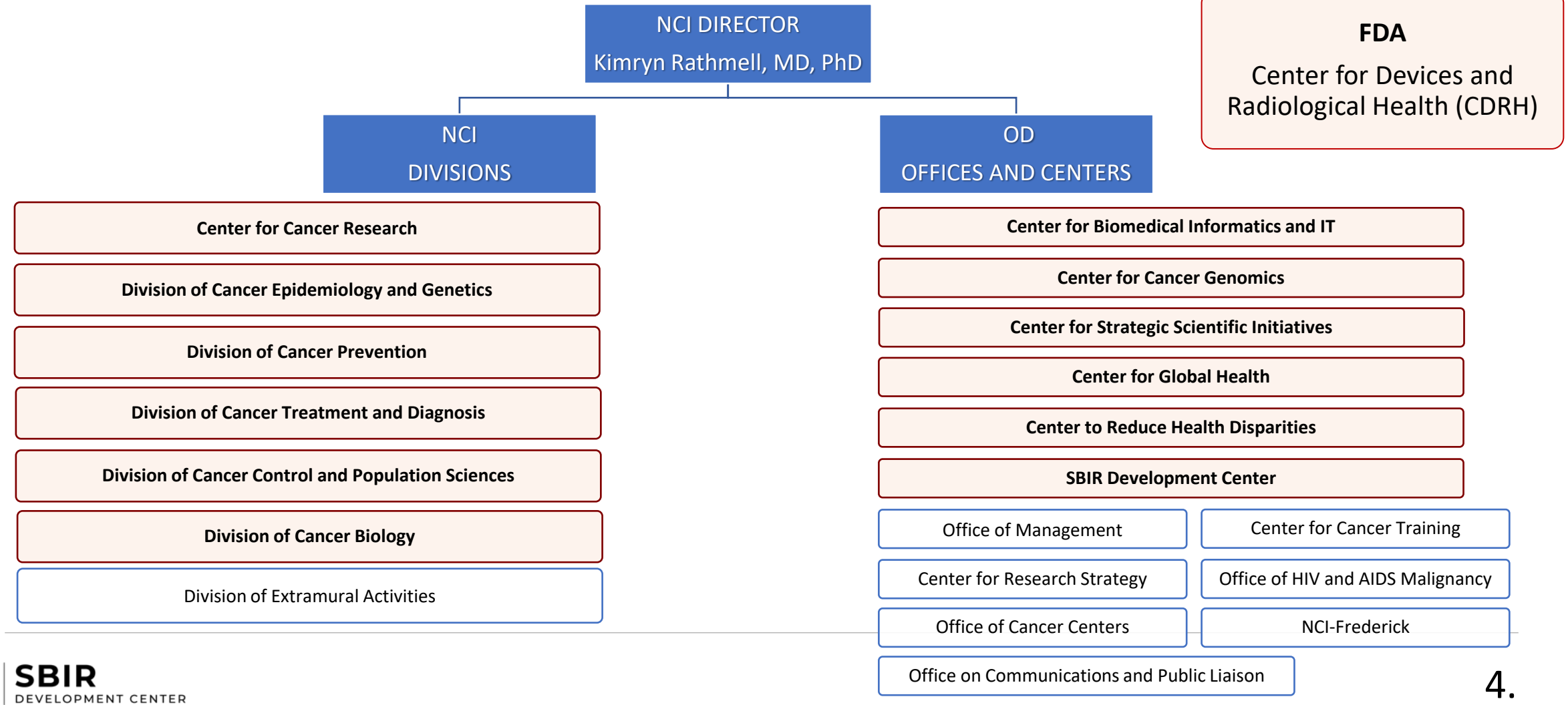
- Advanced Manufacturing to Speed Availability of Emerging Autologous Cell-based Therapies

## Direct Funding to Underrepresented Areas in Our Portfolio

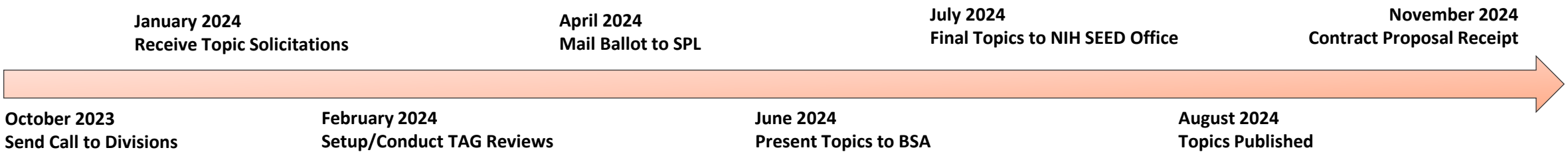
Example:

- Digital Tools to Improve Health Outcomes in Pediatric Cancer Survivors

# HOW DOES NCI SBIR DEVELOP CONTRACT TOPICS?



# CONTRACT TOPIC SELECTION PROCESS – FY2025




**15 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

| 13 Topics | Therapeutics | Clinical Diagnostics & Molecular Analysis | Information Tech & Digital Health | Medical Devices | Research Tools |
|---|---|---|---|---|---|
| | 7 | 2 | 2 | 1 | 1 |

# THERAPEUTICS

| Topic Title | Overall Goal |
| --- | --- |
| **Novel Delivery Systems for RNA-based Cancer Vaccines**<br>▪ *Center for Strategic Scientific Initiatives* | Support the development of new delivery systems with enhanced properties to accelerate the development of RNA-based cancer vaccines.<br><br>***National Cancer Plan (3)*** *develop effective treatments*<br>*Page 6* |
| **Development of Cancer Immunoprevention Agents**<br>▪ *Division of Cancer Prevention*<br>▪ *Division of Cancer Biology* | Advance the development of novel, safe, and efficacious immunopreventive vaccines (DNA, mRNA, peptide) or immunomodulatory drugs (small molecules or biologics) for cancer prevention and interception in well-identified high-risk cohorts (e.g., Lynch syndrome, BRCA, FAP, smokers, asbestos exposed, precancers such as PanIN, IPMN, STIC, PIN, CIN, adenoma, Barrett's esophagus).<br><br>***National Cancer Plan (1)*** *prevent cancer*<br>*Page 7* |

# THERAPEUTICS

| Topic Title | Overall Goal |
| --- | --- |
| **Synthetic Microbes (Excluding Oncolytic Viruses) for Immuno-Oncology Therapies**<br>▪ *Division of Cancer Treatment and Diagnosis* | Support the development of safe and effective immune-modulating synthetic microbes for immuno-oncology (IO) therapeutic use in the clinic.<br><br>***National Cancer Plan (3)*** *develop effective treatments*<br>*Page 8* |
| **Development of Novel Therapeutics for HPV-related Precancer**<br>▪ *Division of Cancer Prevention* | Develop effective HPV therapeutics that can treat chronic HPV infections and/or cause regression of precancers by preventing HPV-related cancers from developing at relevant organ sites (e.g., cervical, anogenital, oropharyngeal).<br><br>***National Cancer Plan (1, 4)*** *prevent cancer; eliminate inequities*<br>*Page 9* |

# THERAPEUTICS

| Topic Title | Overall Goal |
| --- | --- |
| **Precision Nutrition Interventions to Reduce Cancer-Related Symptoms**<br>▪ *Division of Cancer Prevention*<br>▪ *Division of Cancer Control and Population Sciences* | Support the development of new targeted nutritional products for patients experiencing nutrition impact symptoms to help clinical care teams maintain patient's nutritional status, quality of life, and bolster a patient's tolerance for cancer treatment.<br><br>***National Cancer Plan (5)*** *deliver optimal care*<br>*Page 10* |
| **Drug-Loaded Carrier Particles for Improved Oral Delivery for Colon Cancer Prevention**<br>▪ *Division of Cancer Prevention* | Develop oral preventative agents for high-risk patients with Inflammatory Bowel Disease (IBD) to prevent colon cancer.<br><br>***National Cancer Plan (1)*** *prevent cancer*<br>*Page 11* |

# THERAPEUTICS

| Topic Title | Overall Goal |
| --- | --- |
| **Antibody-Drug Conjugates as Radiopharmaceutical Theranostics for Cancer**<br>▪ *Division of Cancer Treatment and Diagnosis* | Improve efficacy of ADCs by labeling them with radionuclides and for a new theranostic treatment strategy that includes diagnostic, imaging-based patient selection followed by two-armed therapy (chemical- and radiation-based).<br><br>***National Cancer Plan (3)*** *develop effective treatments*<br><br>*Page 12* |

# CLINICAL DIAGNOSTICS & MOLECULAR ANALYSIS

| Topic Title | Overall Goal |
| --- | --- |
| **Point of Care Detection of Antibodies Against HPV16/18 E6 and E7 Oncoproteins**<br>▪ *Division of Cancer Prevention* | Support the development and validation of a rapid, point of care (POC) test for Human Papillomavirus (HPV)-related oropharyngeal cancers that includes the separate detection of antibodies against HPV16 and 18 E6 and E7 proteins.<br><br>***National Cancer Plan (1, 2, 4)*** *prevent cancer; detect cancers early; eliminate inequities*<br><br>*Page 13* |
| **Point of Care Technologies for GI Cancer Prevention and Early Detection**<br>▪ *Center for Global Health*<br>▪ *Division of Cancer Prevention*<br>▪ *Division of Cancer Control and Population Sciences* | Advance the development of an affordable and scalable point of care (POC) test that can effectively screen for precancerous conditions and early cancers in the gastrointestinal (GI) tract (esophagus, stomach, small and large intestine, rectum, anus).<br><br>***National Cancer Plan (1, 2)*** *prevent cancer; detect cancers early*<br><br>*Page 14* |

# INFORMATION TECHNOLOGY & DIGITAL HEALTH

| Topic Title | Overall Goal |
| --- | --- |
| **Development of Digital Biomarkers and Endpoints for Clinical Cancer Care**<br>▪ *Division of Cancer Control and Population Sciences*<br>▪ *Division of Cancer Treatment and Diagnosis*<br>▪ *Center for Strategic Scientific Initiatives* | Facilitate the commercial development of digital biomarkers and/or endpoints that can help clinical care teams improve patient care (e.g., remote monitoring of a patient's response to treatment). Digital biomarkers will utilize data from digital health technologies (e.g., heart rate, oxygen saturation, sleep, physical activity, etc.) and demonstrate clinical utility for patients.<br>***National Cancer Plan (5)*** *deliver optimal care*<br>*Page 15* |
| **Digital Twin Software for Optimization of Cancer Radiation Therapy**<br>▪ *Division of Cancer Treatment and Diagnosis* | Development digital twin software that can inform radiation therapy in patient care by utilizing multi-scale data (e.g., molecular, cellular, organ, organism, societal, geographic, modalities available, family history, cost and toxicity) for treatment optimization purposes.<br>***National Cancer Plan (3)*** *develop effective treatments*<br>*Page 16* |

# MEDICAL DEVICES

| Topic Title | Overall Goal |
| --- | --- |
| **Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment**<br>▪ *Center for Strategic Scientific Initiatives*<br>▪ *Division of Cancer Treatment and Diagnosis* | Facilitate the commercial development of wearable sensors that can provide remote patient monitoring and assist clinical care teams in identifying cancer treatment-related toxicities early on.<br><br>***National Cancer Plan (5)*** *deliver optimal care*<br><br>*# This topic is a re-issue*<br><br>*Page 17* |

# RESEARCH TOOLS

| Topic Title | Overall Goal |
| --- | --- |
| **Advanced Biomaterials to Improve Cancer Modeling for Research**<br>▪ *Division of Cancer Biology* | Advance the development of versatile and accessible biomaterial-based tools (kits and reagents) for cancer researchers. Biomaterials should be able to change or adapt in response to tumor initiation, progression, or metastasis (e.g., adaptable response to tumor, changes in stiffness, strain or crosslinking, etc.).<br><br>***National Cancer Plan (3)*** *develop effective treatments*<br><br>*Page 18* |

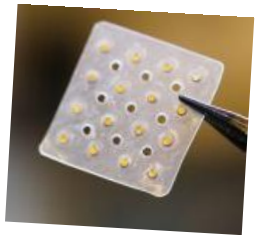
# SUCCESS STORY: CIVATECH

**NIH/NCI 258: Innovative Devices to Protect Radiosensitive Organs and Structures During Radiation Therapy**

**Technology:** CivaSheet®
A brachytherapy device that is truly customizable to a specific patient's condition and offers a unidirectional option to shield healthy tissue.

## SBIR CONTRACT AWARDEE

CivaTech received an SBIR contract award to develop Civasheet® and then followed it up with two SBIR grants for performing clinical validation in pancreatic and lung cancer.



## COMMERCIALLY AVAILABLE

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

## ADDITIONAL PRODUCTS

- CivaString®: a linear, polymer-encapsulated, low-dose-rate brachytherapy source used to treat localized, solid tumors.
- CivaDerm™: temporary radiation therapy product for surface radiation to treat skin cancer and other lesions.

# THANK YOU

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