

MARCH 16, 2021 | NCI BSA MEETING

NCI SBIR FY 2022 CONTRACT TOPICS

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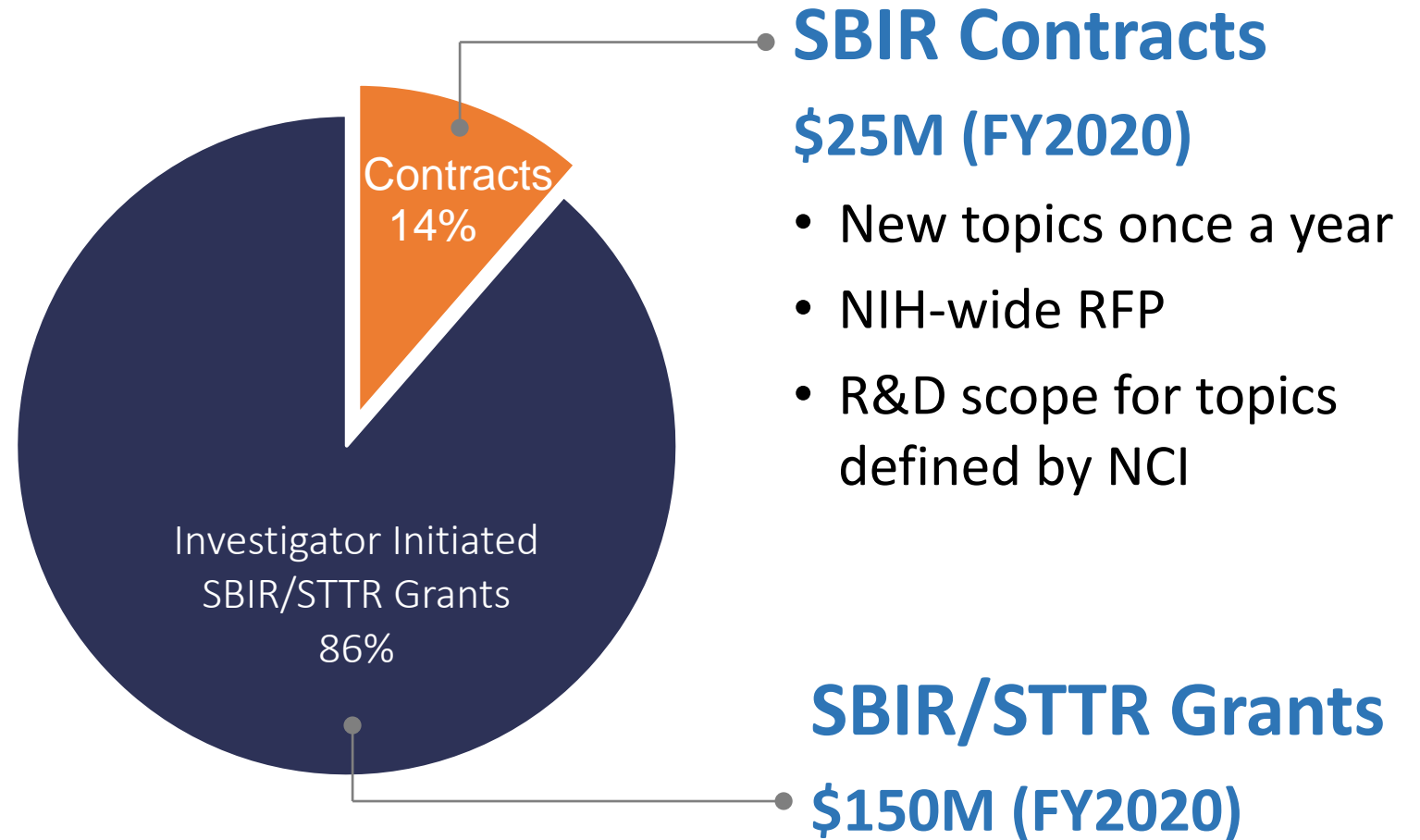
NCI SBIR SUPPORTS GRANTS & CONTRACTS

SBIR

Small Business
Innovation Research
(3.2%)

STTR

Small Business
Technology Transfer
(0.45%)



WHY DOES NCI SBIR FUND R&D CONTRACTS?



Addressing
Specific Cancer
Community
Needs.



Stimulating
Commercialization
in Emerging Areas.

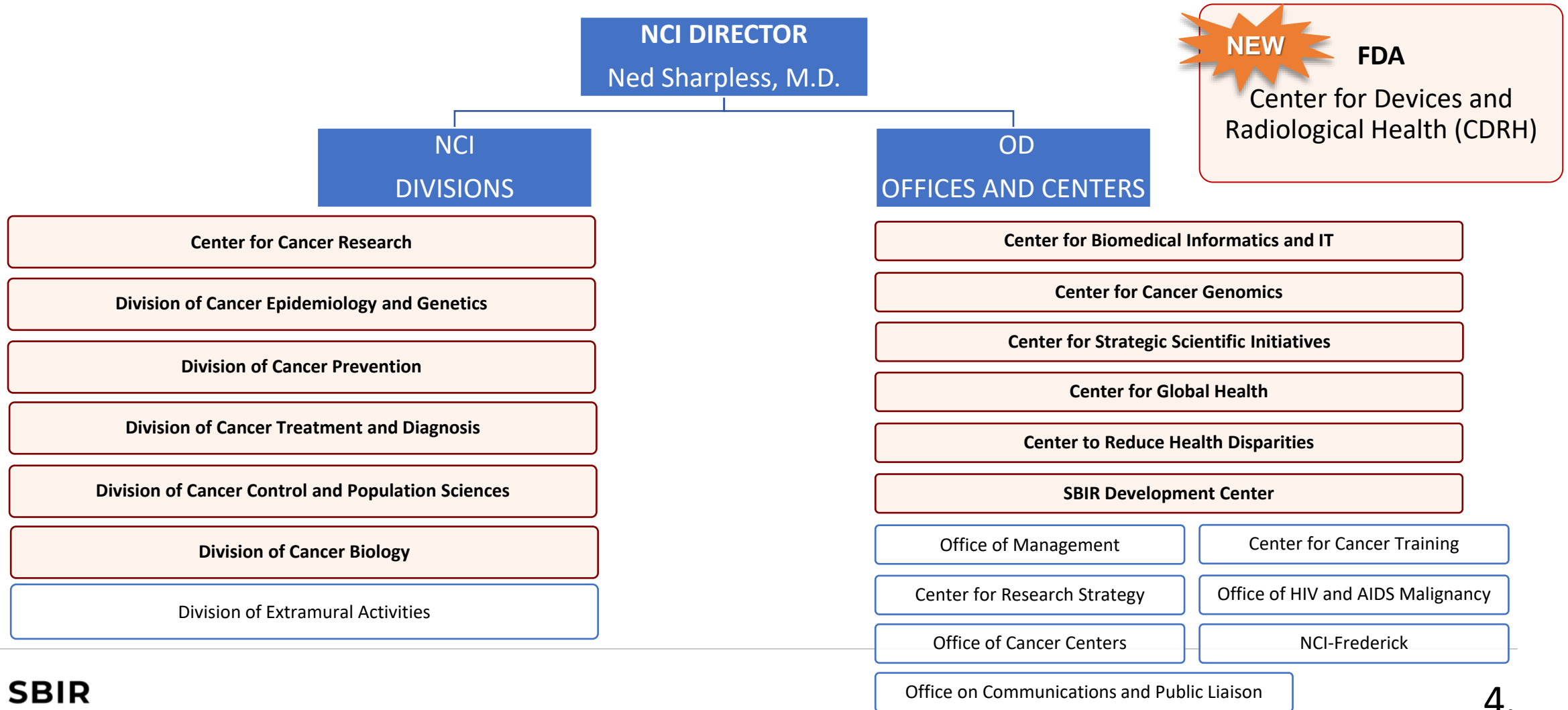


Streamlined
Stepwise Product
Development.

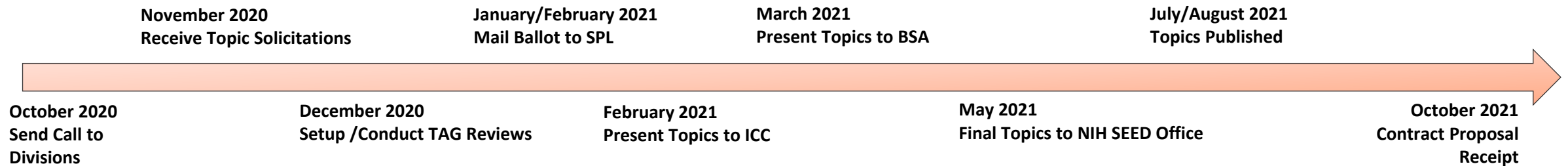


Technology
Transfer from
NIH Labs to
Industry

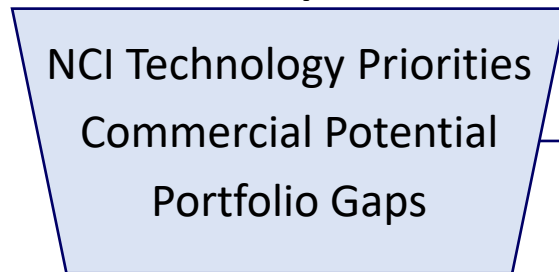
HOW DOES NCI SBIR GET CONTRACT TOPICS?



CONTRACT TOPIC SELECTION PROCESS – FY2022



19 Concept Ideas



Technology Advisory Groups

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

16 Topics	Therapeutics	Medical Devices	Clinical Diagnostics and Molecular Analysis	Information Technology and Bioinformatics	Manufacturing Technologies
	3	3	7	2	1

THERAPEUTICS

Topic Title	Overall Goal
<p data-bbox="180 508 1085 615">Development of Senotherapeutic Agents for Cancer Treatment</p> <ul data-bbox="180 651 945 808" style="list-style-type: none"><li data-bbox="180 651 652 696">▪ <i>Div. of Cancer Biology</i><li data-bbox="180 708 945 753">▪ <i>Div. Cancer Treatment and Diagnosis</i><li data-bbox="180 765 728 808">▪ <i>SBIR Development Center</i>	<p data-bbox="1110 508 2219 665">Support the basic and pre-clinical development of senotherapeutic agents for use in research, neoadjuvant, adjuvant, or combination cancer therapy.</p> <p data-bbox="2232 786 2323 815"><i>Page 7</i></p>
<p data-bbox="180 869 1072 976">Cancer Treatment Technologies for Low-Resource Settings</p> <ul data-bbox="180 1012 945 1169" style="list-style-type: none"><li data-bbox="180 1012 728 1058">▪ <i>SBIR Development Center</i><li data-bbox="180 1069 703 1115">▪ <i>Center for Global Health</i><li data-bbox="180 1126 945 1172">▪ <i>Div. Cancer Treatment and Diagnosis</i>	<p data-bbox="1110 869 2244 1026">Develop or adapt, apply, and validate existing or emerging technologies into low-resource setting-appropriate technologies for <u>cancer treatment</u>.</p> <p data-bbox="2232 1148 2323 1176"><i>Page 8</i></p>

THERAPEUTICS

Topic Title	Overall Goal
<p data-bbox="180 625 945 739">Synthetic Biology Gene Circuits for Cancer Therapy</p> <ul data-bbox="180 768 728 815" style="list-style-type: none"><li data-bbox="180 768 728 815">■ <i>SBIR Development Center</i>	<p data-bbox="1116 625 2193 725">Stimulate the development of gene circuit therapies for cancer.</p> <p data-bbox="1116 739 1574 782"><i># This topic is a re-issue</i></p> <p data-bbox="2237 796 2328 825"><i>Page 9</i></p>

MEDICAL DEVICES

Topic Title	Overall Goal
<p>Developing Unbiased Medical Technologies to Reduce Disparities in Cancer Outcomes</p> <ul style="list-style-type: none"> ▪ <i>Div. of Cancer Control and Population Sciences</i> ▪ <i>SBIR Development Center</i> 	<p>Advance the development of innovative, unbiased medical technologies to reduce disparities in cancer outcomes</p> <p>Rec. (J) developing new enabling cancer technologies Rec. (G) cancer prevention and early detection strategies</p> <p style="text-align: right;"><i>Page 10</i></p>
<p>Ultra-Fast Dose Rate (FLASH) Radiation Detectors and Safety Systems</p> <ul style="list-style-type: none"> ▪ <i>Div. Cancer Treatment and Diagnosis</i> 	<p>Advance the development and/or application of devices, to allow FLASH radiation therapy to be properly evaluated and ultimately translated into the clinic.</p> <p style="text-align: right;"><i>Page 11</i></p>

MEDICAL DEVICES

Topic Title	Overall Goal
<p data-bbox="180 582 868 751">Devices to Treat Secondary Lymphedema Following Cancer Treatment</p> <ul data-bbox="180 768 723 811" style="list-style-type: none"><li data-bbox="180 768 723 811">▪ <i>SBIR Development Center</i>	<p data-bbox="1116 582 2318 793">Support the development of technologies that prevent, reduce, or eliminate lymphedema following removal or radiation of lymph nodes due to cancer in the upper body, i.e. neck, chest, arm(s), or thoracic cavity.</p> <p data-bbox="1116 865 2270 908">Rec. (F) symptom management following cancer treatment.</p> <p data-bbox="2219 919 2326 948"><i>Page 12</i></p>

CLINICAL DIAGNOSTICS & MOLECULAR ANALYSIS

Topic Title	Overall Goal
<p data-bbox="183 478 963 585">New Technologies to Analyze Extra-Chromosomal DNA in Cancer</p> <ul data-bbox="183 625 1006 671" style="list-style-type: none"><li data-bbox="183 625 1006 671">▪ <i>Center for Strategic Scientific Initiatives</i>	<p data-bbox="1116 478 2323 692">Develop new approaches or modify existing approaches to understand ecDNA and their role in cancer. This contract topic aims to develop new tools that are critically needed to analyze ecDNA sequence, structure and regulation.</p> <p data-bbox="1116 756 2254 806">Rec. (J) development of new enabling cancer technologies</p> <p data-bbox="2216 813 2323 849"><i>Page 13</i></p>
<p data-bbox="183 949 963 1056">3D Spatial Omics for Molecular and Cellular Tumor Atlas Construction</p> <ul data-bbox="183 1078 993 1235" style="list-style-type: none"><li data-bbox="183 1078 649 1120">▪ <i>Div. of Cancer Biology</i><li data-bbox="183 1135 993 1178">▪ <i>Center for Strategic Scientific Initiatives</i><li data-bbox="183 1192 726 1235">▪ <i>SBIR Development Center</i>	<p data-bbox="1116 949 2216 1106">Advance the development and dissemination of imaging workflows capable of omics-level measurements in thick tissue resections or whole biopsy cores.</p> <p data-bbox="1116 1120 1617 1170"><i># This topic is a re-issue</i></p> <p data-bbox="1116 1185 2267 1235">Rec. (J) development of new enabling cancer technologies,</p> <p data-bbox="1116 1242 1974 1292">Rec. (I) generation of human tumor atlases.</p> <p data-bbox="2216 1292 2323 1328"><i>Page 14</i></p>

CLINICAL DIAGNOSTICS & MOLECULAR ANALYSIS

Topic Title	Overall Goal
<p data-bbox="180 478 1039 649">Understanding Cancer Tumor Genomic Results: Technology Applications for Community Providers</p> <ul data-bbox="180 692 1006 1185" style="list-style-type: none"><li data-bbox="180 692 955 735">▪ <i>Div. Cancer Treatment and Diagnosis</i><li data-bbox="180 749 955 842">▪ <i>Div. of Cancer Control and Population Sciences</i><li data-bbox="180 863 700 906">▪ <i>Center for Global Health</i><li data-bbox="180 921 942 1013">▪ <i>Office of Communications and Public Liaison</i><li data-bbox="180 1035 726 1078">▪ <i>SBIR Development Center</i><li data-bbox="180 1092 1006 1185">▪ <i>BRP Implementation Team, Network for Direct Patient Engagement</i>	<p data-bbox="1116 478 2267 628">Design and develop tools, technologies, and/or products to help oncology providers and their patients with latest NGS knowledge.</p> <p data-bbox="1116 649 1567 692"><i># This topic is a re-issue</i></p> <p data-bbox="1116 763 2318 806">Rec. (A) establishing a network for direct patient engagement.</p> <p data-bbox="2216 1120 2331 1156"><i>Page 15</i></p>

CLINICAL DIAGNOSTICS & MOLECULAR ANALYSIS

Topic Title	Overall Goal
<p>Advanced Sample Processing Platforms for Downstream Single-Cell Multi-Omic Analysis</p> <ul style="list-style-type: none"> ▪ <i>Div. Cancer Treatment and Diagnosis</i> ▪ <i>Div. of Cancer Control and Population Sciences</i> ▪ <i>SBIR Development Center</i> 	<p>Integrate the preanalytical workflow from tumor cell dissociation/isolation, enrichment, tracking, cell lysis, to biomolecular isolation on a single platform to enable single cell multimodal-omic analysis.</p> <p>Rec. (J) development of new enabling cancer technologies Rec. (I) generation of human tumor atlases.</p> <p style="text-align: right;"><i>Page 16</i></p>
<p>Cancer Prevention and Diagnosis Technologies for Low-Resource Settings</p> <ul style="list-style-type: none"> ▪ <i>SBIR Development Center</i> ▪ <i>Center for Global Health</i> ▪ <i>Div. Cancer Treatment and Diagnosis</i> ▪ <i>Div. Cancer Prevention</i> 	<p>Develop or adapt, apply, and validate existing or emerging technologies into low-resource setting-appropriate technologies for <u>cancer prevention and/or diagnosis</u>.</p> <p style="text-align: right;"><i>Page 17</i></p>

CLINICAL DIAGNOSTICS & MOLECULAR ANALYSIS

Topic Title	Overall Goal
<p data-bbox="178 506 1070 549">At-Home Screening for Hepatitis C Virus</p> <ul data-bbox="178 585 726 685" style="list-style-type: none"><li data-bbox="178 585 662 628">▪ <i>Div. Cancer Prevention</i><li data-bbox="178 635 726 685">▪ <i>SBIR Development Center</i>	<p data-bbox="1108 506 2318 778">Goal: Develop and validate a rapid, sample-to-answer POC test for HCV exposure or active infection that can be used at home with non-invasive specimen that can be collected at home and achieves the same analytic performance as predicate tests.</p> <p data-bbox="2216 792 2318 821"><i>Page 18</i></p>
<p data-bbox="178 885 1070 992">Quantitative Biomarkers as Medical Device Development Tools for Cancer</p> <ul data-bbox="178 1013 815 1113" style="list-style-type: none"><li data-bbox="178 1013 815 1056">▪ <i>Food and Drug Administration</i><li data-bbox="178 1063 726 1113">▪ <i>SBIR Development Center</i>	<p data-bbox="1108 885 2318 992">Goal: Stimulate the participation of small businesses in the FDA's MDDT Program to develop quantitative biomarker tests.</p> <p data-bbox="2216 1113 2318 1142"><i>Page 19</i></p>

INFORMATION TECHNOLOGY & BIOINFORMATICS

Topic Title	Overall Goal
<p data-bbox="180 482 1075 651">Development of Computer-Aided Diagnosis Tools for Upper and Lower Gastrointestinal Tract Cancer Prevention</p> <ul data-bbox="180 689 726 786" style="list-style-type: none"><li data-bbox="180 689 665 729">▪ <i>Div. Cancer Prevention</i><li data-bbox="180 743 726 786">▪ <i>SBIR Development Center</i>	<p data-bbox="1113 482 2308 779">Advance the development and application of artificial intelligence-based algorithms to improve the visual human-based determination of precancerous lesions examined through visual inspection of upper and lower endoscopies.</p> <p data-bbox="2219 793 2321 822"><i>Page 20</i></p>
<p data-bbox="180 875 1021 1043">Evaluation Datasets as Medical Device Development Tools for Testing Cancer Technologies</p> <ul data-bbox="180 1061 963 1275" style="list-style-type: none"><li data-bbox="180 1061 817 1100">▪ <i>Food and Drug Administration</i><li data-bbox="180 1115 726 1155">▪ <i>SBIR Development Center</i><li data-bbox="180 1169 963 1275">▪ <i>Center for Biomedical Informatics and Information Technology</i>	<p data-bbox="1113 875 2308 1086">Stimulate the participation of small businesses in the FDA's MDDT program to develop and demonstrate the utility of qualified datasets as MDDTs to assess medical devices subject to regulation by CDRH.</p> <p data-bbox="2219 1158 2321 1186"><i>Page 21</i></p>

MANUFACTURING TECHNOLOGIES

Topic Title	Overall Goal
<p data-bbox="180 611 1080 786">Advanced Manufacturing to Speed Availability of Emerging Autologous Cell-based Therapies</p> <ul data-bbox="180 801 945 953" style="list-style-type: none"><li data-bbox="180 801 945 843">▪ <i>Div. Cancer Treatment and Diagnosis</i><li data-bbox="180 858 728 901">▪ <i>SBIR Development Center</i><li data-bbox="180 915 473 953">▪ <i>NCI Director</i>	<p data-bbox="1110 611 2313 768">Stimulate the development of advanced manufacturing technologies that substantially improve the speed and cost of producing autologous cell-based therapies.</p> <p data-bbox="1110 782 1574 825"><i># This topic is a re-issue</i></p> <p data-bbox="1110 896 2257 996">Rec. (B) strategies to discover and evaluate novel immune-based approaches.</p> <p data-bbox="2219 1011 2326 1039"><i>Page 22</i></p>

SUCCESS STORY: CIVATECH

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

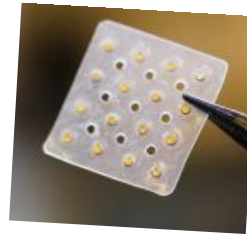


Technology: CIVASHEET (A brachytherapy device that is truly customizable to a specific patient's condition and offers a unidirectional option to shield healthy tissue.)



FIRST CONTRACT AWARDED 2010

Civatech received SBIR award to develop Civasheet and then followed it up with two SBIR grants for performing clinical validation in pancreatic and lung cancer



COMMERCIALY AVAILABLE

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

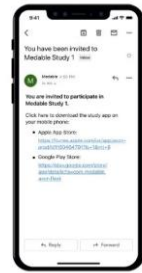
It has been reported that physicians at VCU Massey Cancer Center in Richmond, VA are the first in the world to successfully implant a new bio-absorbable, internal radiation treatment known as **CivaSheet®** to treat a patient with resectable pancreatic cancer

SUCCESS STORY: MEDABLE

NIH/NCI 363: Connecting Cancer Caregivers to Care Teams: Digital Platforms to Support Informal Cancer Caregiving



Technology: Data Driven,
De-centralized Clinical Trial
Platform for Global Clinical Trials



2018

Medable received two NCI SBIR Contracts for developing modules that support their clinical trial platform.

DIGITAL CLINICAL TRIAL PLATFORM

Global Screening and Enrollment

Virtual Consent

Telemedicine & ePRO

Electronic Clinical Outcome Assessment

November 2020

Medable announced \$91 million in new funding to accelerate the life sciences industry's shift to digital and decentralized clinical trials

ECONOMIC IMPACT STUDY

1. Quantify the contribution of the NCI SBIR/STTR program to the U.S. economy
2. Determine key patient and societal impacts resulting from technologies funded by the NCI SBIR/STTR program



Test Cohort

- 690 Phase II SBIR/STTR grant awards
- Awards made between 1998 – 2010
- 444 Companies
- \$787 Million

Study timeline: September 2017 – September 2018

sbir.cancer.gov/impact

ECONOMIC IMPACT



**\$9.1
BILLION**

in total sales to date of
products and services
resulting from the NCI
SBIR/STTR Phase II awards



**\$26.1
BILLION**

in total economic
output nationwide



368

awards with sales,
royalties, and follow-on
R&D funding



**\$2.9
BILLION**

in new tax revenues
(federal, state, and local)



**\$8.1
BILLION**

in labor income



107,918

new jobs created with an
average compensation of
\$75,385

THANK YOU
