NCAB WORKING GROUP REPORT ON THE NATIONAL CANCER INSTITUTE SMALL BUSINESS INNOVATION RESEARCH PROGRAM

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OUTLINE

• Overview of NCI SBIR Program
• Charge to the Working Group
• Working Group Findings
• 2018 Economic Impact Study
# Program Goals:

1. Stimulate technological innovation
2. Increase private-sector commercialization of federal research and development
3. Increase small business participation in federally funded research and development
4. Foster participation by minority and disadvantaged companies in technological innovation

## Small Business Innovation Research (SBIR)

Engages small businesses in Federal R&D with commercialization potential. (FY18 Set-aside 3.2%)

*Federal agencies with extramural R&D budget >$100M*

## Small Business Technology Transfer (STTR)

Facilitates R&D between U.S. research institutions and small businesses with commercialization potential. (FY18 Set-aside 0.45%)

*Federal agencies with extramural R&D budget >$1B*

## SBIR & STTR

<table>
<thead>
<tr>
<th>Program</th>
<th>Combined Budget for FY19</th>
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<tbody>
<tr>
<td>SBIR &amp; STTR</td>
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<tr>
<td>NIH</td>
<td>~$1,145M</td>
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<td>NCI</td>
<td>~$173M</td>
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NCI SBIR/STTR Three-Phase Program

**Phase I**
- Proof-of-Concept
- Up to $300K over 6 to 12 months

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

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

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

**NCI SBIR PHASE IIB BRIDGE AWARD**

**Crossing the Valley of Death**

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

Major Portfolio Areas (2018)
~475 Total Projects

- Grants: 89%
- Contracts: 11%

Therapeutics: 43%
- Devices for Cancer Therapy: 11%
- Imaging: 14%
- In Vitro Diagnostics: 16%
- Cancer Biology: 8%
- Cancer Control and Epidemiology: 8%
Charge to the Working Group
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
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<tbody>
<tr>
<td>1</td>
<td>What is the best way to review SBIR/STTR applications within the NIH peer review environment?</td>
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<tr>
<td>2</td>
<td>Are the current award sizes appropriate for SBIR/STTR Phase I and Phase II?</td>
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<tr>
<td>3</td>
<td>What is the optimal SBIR/STTR portfolio balance (therapeutics, devices, and diagnostics)?</td>
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<tr>
<td>4</td>
<td>How should the NCI foster diversity (geographic, gender, ethnic) within the SBIR/STTR portfolio?</td>
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<td>5</td>
<td>Are the assistance programs offered by the SBIR Development Center effective? Should the NCI consider new programs?</td>
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<tr>
<td>6</td>
<td>What are the best ways for the NCI to support academics who are interested in using the SBIR program to commercialize their technologies?</td>
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<td>7</td>
<td>How should the SBIR program partner with the NCI intramural program, NIH Clinical Center, the Frederick National Lab for Cancer Research, and other NCI programs (e.g., NExT program)?</td>
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<tr>
<td>8</td>
<td>What are the appropriate metrics that the NCI should use to evaluate the SBIR/STTR program?</td>
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Working Group Members

Co-Chairs

Elizabeth M Jaffee, M.D.
Johns Hopkins University

Mel Billingsley, Ph.D.
Life Science Greenhouse of Central Pennsylvania
Pennsylvania State University

Members

Errol Arkilic, Ph.D.
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Aruna Gambhir, M.B.A.
CellSight Technologies, Inc.

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Canaan Partners

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Alamar Biosciences

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Lumos Pharma

Melinda Richter
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Boston Children’s Hospital
Convelo Therapeutics

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Hatteras Ventures Partners

Robert Schreiber, Ph.D.
Washington University School of Medicine

Scott Weir, Pharm.D., Ph.D.
The University of Kansas Cancer Center

Executive Secretary

Michael Weingarten, M.A.
Director, SBIR Development Center
National Cancer Institute
Overall Assessment

NCI SBIR/STTR Program Strengths

• SBIR/STTR programs effectively support the mission of the NCI
• Strong centralized management and good flexibility
• High percentage of projects funded the development of new treatment options
• Significant leverage of NIH funds from private investments and company acquisitions
• Highly competitive grants process – success rates are 10-15% (P1) and 20-25% (P2)
• Peer-review and SBIR/STTR funding substantially de-risk early-stage technologies
• Successful SBIR/STTR grantees have a significant impact on cancer burden
Working Group Recommendations
1. What is the best way to review SBIR/STTR applications within the NIH peer review environment?

NIH peer review criteria
- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

NIH SBIR Peer Review Improvement Committee (est. 2016)
- Optimize review processes
- Improve composition of review panels
1. What is the best way to review SBIR/STTR applications within the NIH peer review environment?

**WORKING GROUP RECOMMENDATIONS**

- Prioritize NIH Peer Review Committee’s recommendations
  - Modify standard NIH review criteria definitions to reflect SBIR/STTR
  - Recruit more reviewers with business development expertise
  - Add scored criterion for Phase II – company’s commercialization strategy

- Reduce receipt-to-award time to 7 months (currently 7.6 months, down from 12 months in 2013)

- Reduce time-to-award for SBIR contracts to 9 months (currently 11 months)
2 & 3. Are the current award sizes appropriate for SBIR/STTR Phase I and Phase II? What is the optimal SBIR/STTR portfolio balance?

### Technology Sectors

<table>
<thead>
<tr>
<th></th>
<th>Biopharma</th>
<th>Diagnostics</th>
<th>Devices</th>
<th>Health IT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All awards</strong></td>
<td>40-50 (45)</td>
<td>15-20 (18)</td>
<td>28-31 (29)</td>
<td>6-9 (8)</td>
</tr>
<tr>
<td><strong>Contracts</strong></td>
<td>23-40 (30)</td>
<td>18-36 (27)</td>
<td>20-33 (26)</td>
<td>12-26 (18)</td>
</tr>
</tbody>
</table>

### Phase I, Phase II, Phase IIB

<table>
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<tr>
<th></th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase IIB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statutory budget limits</td>
<td>$225K</td>
<td>$1.5M</td>
<td>$1.5M</td>
</tr>
<tr>
<td>NCI waiver topics (include many cancer-focused technologies)</td>
<td>$300K</td>
<td>$2.0M</td>
<td>$4.0M (≥1:1 matching expected)</td>
</tr>
</tbody>
</table>
2 & 3. Are the current award sizes appropriate for SBIR/STTR Phase I and Phase II? What is the optimal SBIR/STTR portfolio balance?

**WORKING GROUP RECOMMENDATIONS**

- Create new SBIR “Concept” Grant
  - Target – high-risk/high-reward projects and validation studies
  - Start – fund 10 projects at $100-150K each

- Use supplements to help Phase I awardees reach value-creating milestones

- Increase SBIR/STTR Phase I award size to $400K (currently $300K)
4. How should the NCI foster diversity (geographic, gender, ethnic) within the SBIR/STTR portfolio?

Involvement of women and underrepresented minorities as non-majority owners in funded small businesses is significant, but there is still room for improvement.
4. How should the NCI foster diversity (geographic, gender, ethnic) within the SBIR/STTR portfolio?

Currently and previously available programs

**Application Assistance Program**
- Joint pilot program (3 NIH Institutes)
- Focus – underrepresented small businesses

**Diversity Supplement Program**
- Small business specific funding opportunity – new in 2018
- NCI – 4 applications in first 6 months (up from 1 application in last 6 years of general program)
4. How should the NCI foster diversity (geographic, gender, ethnic) within the SBIR/STTR portfolio?

WORKING GROUP RECOMMENDATIONS

• Implement survey at time-of-award
  - Model after survey developed by Working Group
  - Collect metrics on small businesses – company founders, owners, leaders

• Increase women and minority participation on review panels
5. Are the assistance programs offered by the SBIR Development Center effective? Should the NCI consider new programs?
5. Are the assistance programs offered by the SBIR Development Center effective? Should the NCI consider new programs?

WORKING GROUP RECOMMENDATIONS

• Initiate an FDA regulatory assistance program
  • Educational webinars, facilitated interactions
  • Resources webpage focused on small businesses

• Establish a peer-to-peer mentoring program
6. What are the best ways for the NCI to support academics who are interested in using the SBIR program to commercialize technologies?
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WORKING GROUP RECOMMENDATIONS

• Connect academic investigators with SBIR/STTR
  • Investor events
  • Regional NCI I-Corps entrepreneurship training programs
  • Encourage entrepreneurs from NCI-funded Cancer Centers

• Create portfolio of resources for academic technology transfer offices
  • Successful strategies developed at various cancer centers
  • Facilitate translational research, tech transfer, and entrepreneurship
7. How should the SBIR program partner with other NIH and NCI Programs?

National Cancer Institute

- NCI Technology Transfer Center (TTC)
- NCI Center for Cancer Research (CCR)
- NCI Developmental Therapeutics Program (DTP)
- Frederick National Laboratory for Cancer Research (FNLCR)
7. How should the SBIR program partner with other NIH and NCI Programs?

**WORKING GROUP RECOMMENDATIONS**

- Establish postdoctoral training program
  - Partner – NCI Technology Transfer Center and Center for Cancer Research
  - Focus – grantsmanship, entrepreneurship, tech transfer skills

- Enhance coordination between SBIR and NCI Resources like the NExT program and FNLCR
  - NCI Experimental Therapeutics (NExT) program – offers drug development services
  - SBIR administrative supplements to strengthen the company’s project data package for a future NeXT application
8. What are the appropriate metrics that the NCI should use to evaluate the SBIR/STTR program?
8. What are the appropriate metrics that the NCI should use to evaluate the SBIR/STTR program?

WORKING GROUP RECOMMENDATIONS

• Implement intake survey for awardees
  • Intended product/development stage
  • Commercialization milestones
  • Business/financial metrics
  • Leadership make-up metrics

• Repeat Economic Impact study every 5 years
Priority Goals for NCI SBIR/STTR Program

- Increase Phase I award size
- Use supplements to advance companies to value-creating milestones
- Develop FDA regulatory assistance program
- Develop postdoctoral training program in entrepreneurship and tech transfer
- Continue and enhance metrics collection
- Promote diversity
- Reduce time-to-award for SBIR contracts
- Implement SBIR “Concept grant”
Return on Investment
2018 Economic Impact Study
“Return On Investment”

$787M in Phase II funding between 1998 – 2010 led to:

- **247 products** commercially available
- **$9.1B in sales** of SBIR/STTR-funded technologies
- **Average sale was $13.3M**, ~12X the average award amount of $1.1M
- **107,918 new jobs** in the U.S. with an average salary of $75,386 per worker (through 2018)
- **$2.93B in tax revenue**
- **$26.1B added to the U.S. economy** (through 2018)
SBIR/STTR Impact Study: Purpose

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

All Phase II SBIR/STTR Grants from 1998 – 2010
690 Awards, 444 Companies
$787 Million

Study timeline: September 2017 – September 2018
SBIR/STTR Impact Evaluation: Overview

**DATA COLLECTION**

Data were collected via phone interview with >1 person associated with the technology and knowledge of the SBIR award.

<table>
<thead>
<tr>
<th>Basic Economic Questions</th>
<th>Data Collected on 91% of Companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Total sales of new products and services (including R&amp;D) related to NCI SBIR/STTR-developed technology?</td>
<td>Reasons for High Response Rate</td>
</tr>
<tr>
<td>✓ Other sales (licensing income, sales by licensees or spin-out companies)?</td>
<td>✓ Purpose and value of study clearly communicated</td>
</tr>
<tr>
<td>✓ Other economic impacts (outside investments in company, new company creation, sale of company)?</td>
<td>✓ Official letter from NCI SBIR director</td>
</tr>
<tr>
<td></td>
<td>✓ Pledged confidentiality</td>
</tr>
<tr>
<td></td>
<td>✓ Extensive research to find contacts</td>
</tr>
<tr>
<td></td>
<td>✓ Concise survey</td>
</tr>
<tr>
<td></td>
<td>✓ Persistent researchers</td>
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IMPLAN Model

INPUT

Money that went into the economy for a specific activity, such as R&D.

- NCI SBIR Phase II Awards
- Commercial Sales
- Follow-On R&D
- Licensee Royalties
- Sales by Licensees
- Sales by Spin-Out Companies

Total: $9.96B

Uses US Dept. of Commerce data to model how money going into a specific sector affects the economy.

- $$ value for each product assigned to 1 of 536 sectors
- Each sector has a distinct multiplier
- Sectors include:
  - Surgical and medical instrument manufacturing
  - Pharmaceuticals

OUTPUT

Induced Impact:
- Payroll spending
  - Huge number of small transactions

$7.01B

Indirect Impact:
- Inter-industry purchases
  - Moderate number of large transactions

$9.20B

Direct Impact:
- Initial economic activity
  - Few very-large transactions

$9.93B

Total: $9.96B

An Input/Output model of economic impact.

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“Illumina used SBIR funding to develop the base technology that went into the Infinium array…. At Illumina, we had at least one project for which we couldn’t get SBIR funding because we lost eligibility, and that project never got done. So sometime, projects don’t ever start without SBIR funding.”

-Kevin Gunderson
PI on Illumina SBIR and creator of Infinium
# Case: Naviscan


<table>
<thead>
<tr>
<th>Proof of Concept</th>
<th>PROTOTYPE</th>
<th>CLINICAL EVALUATION</th>
<th>FDA APPROVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solo II™ High-Resolution Breast PET Scanner</td>
<td><img src="image1" alt="Solo II™" /></td>
<td></td>
<td>(2003)</td>
</tr>
<tr>
<td>First clinical dedicated breast PET scanner</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Stereo Navigator</td>
<td><img src="image2" alt="Stereo Navigator" /></td>
<td></td>
<td>(2008)</td>
</tr>
<tr>
<td>PEM-guided biopsy system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gamma Medica LumaGEM®</td>
<td><img src="image3" alt="Gamma Medica LumaGEM®" /></td>
<td></td>
<td>(2011)</td>
</tr>
<tr>
<td>Award-winning Molecular Breast Imaging Technology</td>
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</tbody>
</table>

Naviscan was acquired by CMR in 2013 and Gamma Medica was acquired by CMR Naviscan in 2013. CMR Naviscan now owns THREE NCI SBIR-funded breast cancer imaging technologies.

"The SBIR program was instrumental in funding the company from an early developmental stage which might have seemed a bit too risky for most venture capital groups....Naviscan’s SBIR-funded research helped us to get through the early phase of the clinical trials required for FDA-clearance, which was opportunistically parlayed into venture-backed funds to facilitate commercialization."

- Paul Mirabella
Naviscan’s chairman and CEO
Patient Impact

Of products requiring regulatory approval:

- 71 FDA Approved products
- 127 products still in pre-FDA Development
- 263 products failed before or during clinical testing
247 commercially available products today that were supported by NCI SBIR/STTR awards between 1998 - 2010

Patient Impact

What improvements for cancer patients resulted from the NCI SBIR/STTR Funding?

- Provide a treatment option for a subgroup of patients who previously lacked options
- Reduce invasiveness of a treatment or procedure
- Reduce hospitalization time/# for a procedure
- Reduce # of follow-up visits
- Other