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

February 2019

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OUTLINE

NATIONAL CANCER INSTITUTE SBIR DEVELOPMENT CENTER

- Overview of NCI SBIR Program
- Charge to the Working Group
- Working Group Findings
- 2018 Economic Impact Study

SBIR & STTR

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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 Combined Budget for FY19

~$1,145M at NIH

~$173M at NCI

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

NCI SBIR/STTR Three-Phase Program

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

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

- 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**

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

NCI SBIR/STTR Portfolio

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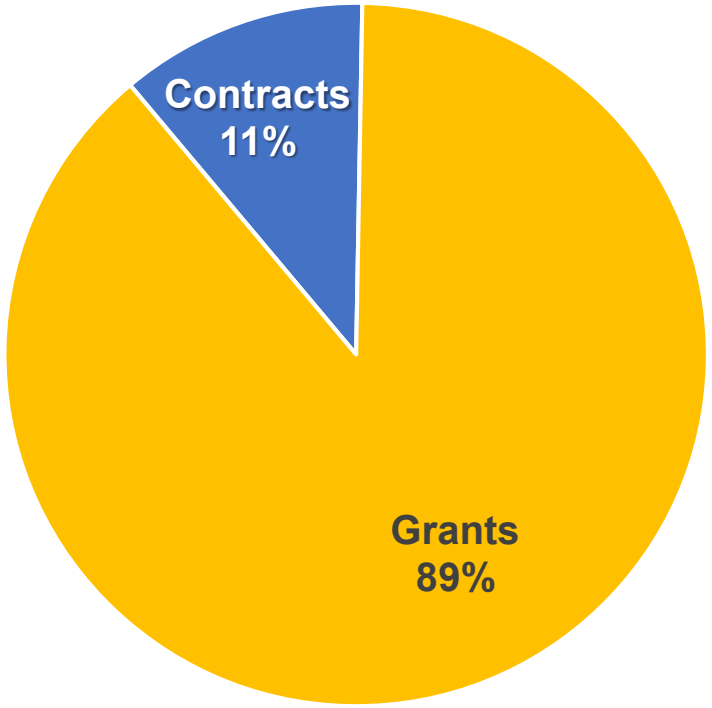
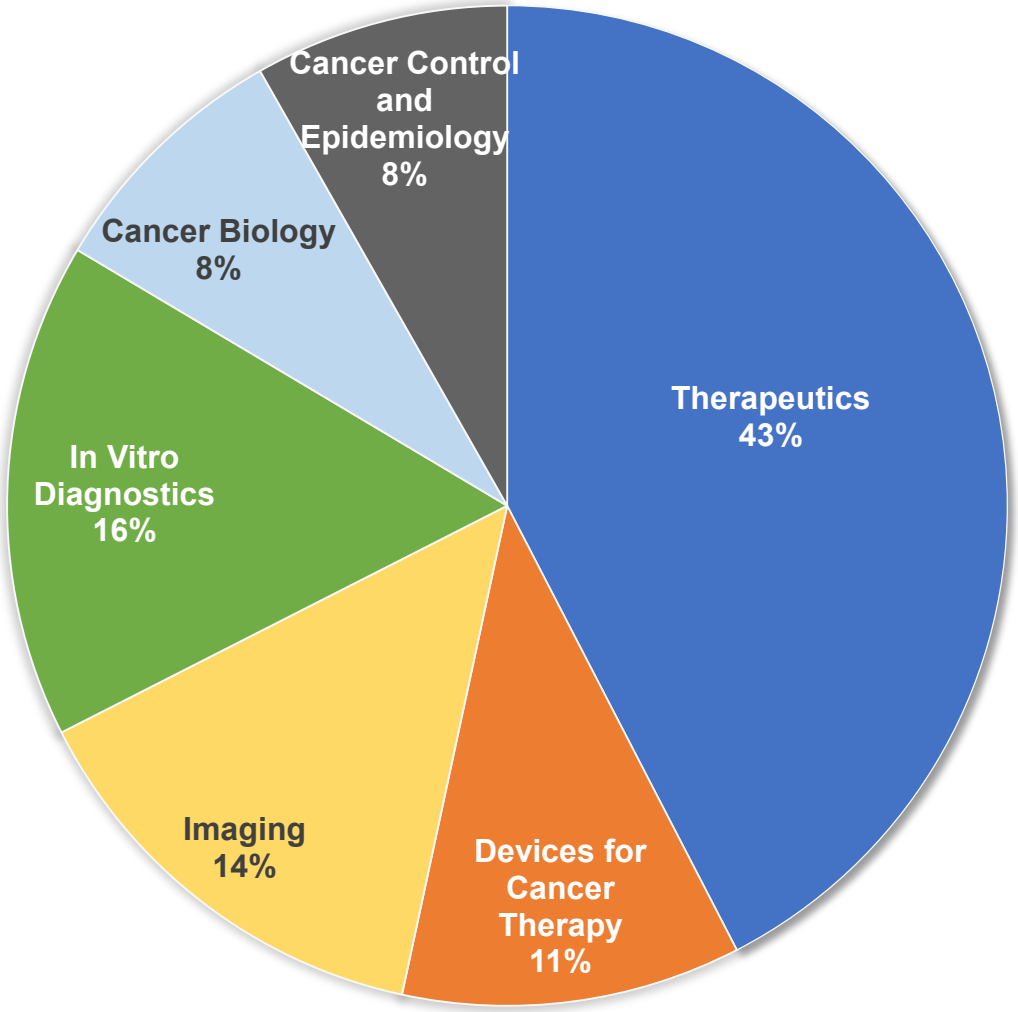
Major Portfolio Areas (2018)

~475 Total Projects





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Charge to the Working Group

Evaluate the NCI SBIR/STTR Program in 8 Areas

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1	What is the best way to review SBIR/STTR applications within the NIH peer review environment?
2	Are the current award sizes appropriate for SBIR/STTR Phase I and Phase II?
3	What is the optimal SBIR/STTR portfolio balance (therapeutics, devices, and diagnostics)?
4	How should the NCI foster diversity (geographic, gender, ethnic) within the SBIR/STTR portfolio?
5	Are the assistance programs offered by the SBIR Development Center effective? Should the NCI consider new programs?
6	What are the best ways for the NCI to support academics who are interested in using the SBIR program to commercialize their technologies?
7	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)?
8	What are the appropriate metrics that the NCI should use to evaluate the SBIR/STTR program?

Working Group Members

NATIONAL CANCER INSTITUTE SBIR DEVELOPMENT CENTER

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Executive Secretary

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Director, SBIR Development Center
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Overall Assessment

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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

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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 % range from 2013-2017 (average)			
	Biopharma	**Diagnostics**	**Devices**	**Health IT**
All awards	40-50 (45)	15-20 (18)	28-31 (29)	6-9 (8)
Contracts	23-40 (30)	18-36 (27)	20-33 (26)	12-26 (18)

	Phase I	**Phase II**	**Phase IIB**
Statutory budget limits	$225K	$1.5M	$1.5M
NCI waiver topics (include many cancer-focused technologies)	$300K	$2.0M	$4.0M (≥1:1 matching expected

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

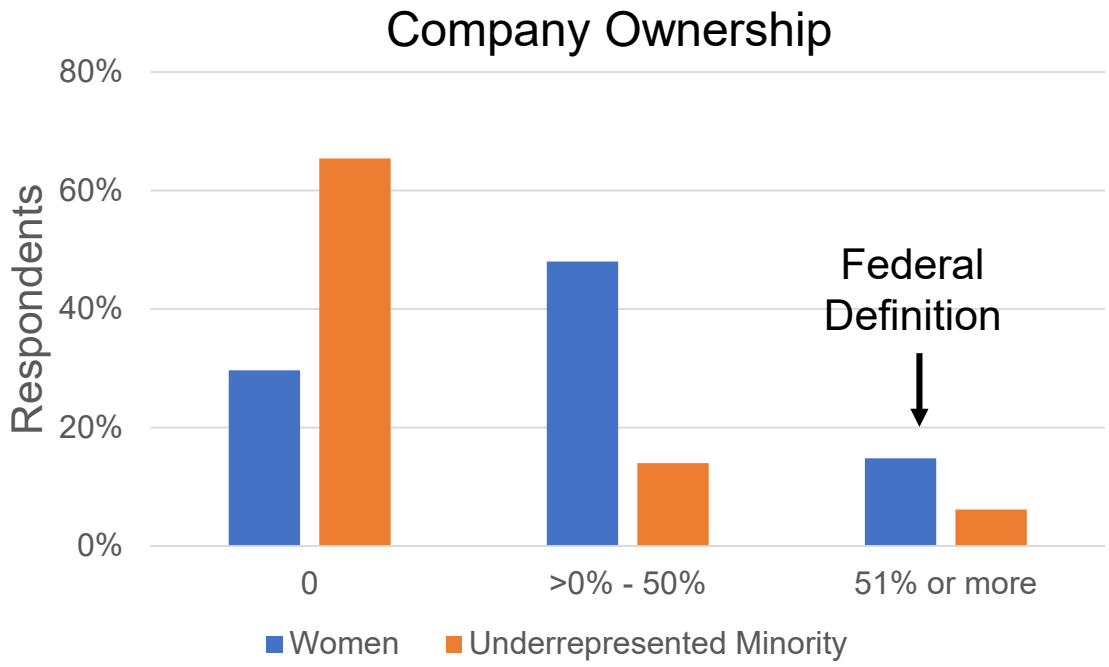
- Create new SBIR "Concept" Grant
  - Target – high-risk/high-reward projects and validation studies
  - Start – fund 10 projects at $100-150K each
- Use supplements to help Phase I awardees reach value-creating milestones
- Increase SBIR/STTR Phase I award size to $400K (currently $300K)

4. How should the NCI foster diversity (geographic, gender, ethnic) within the SBIR/STTR portfolio?

2018 NCI SBIR/STTR Survey of Awardees

44% female executive

17% minority executive



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)

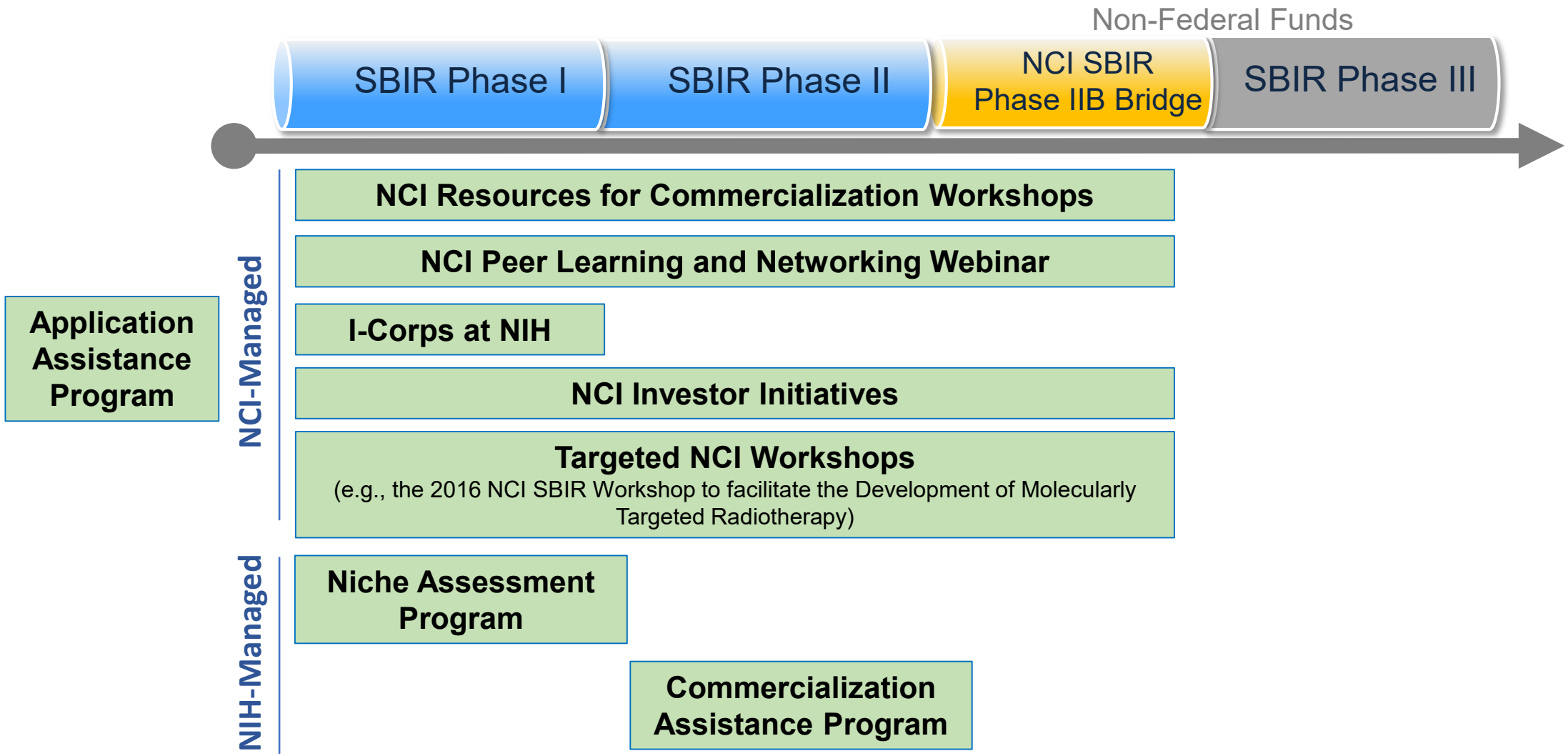
4. How should the NCI foster diversity (geographic, gender, ethnic) within the SBIR/STTR portfolio?

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?



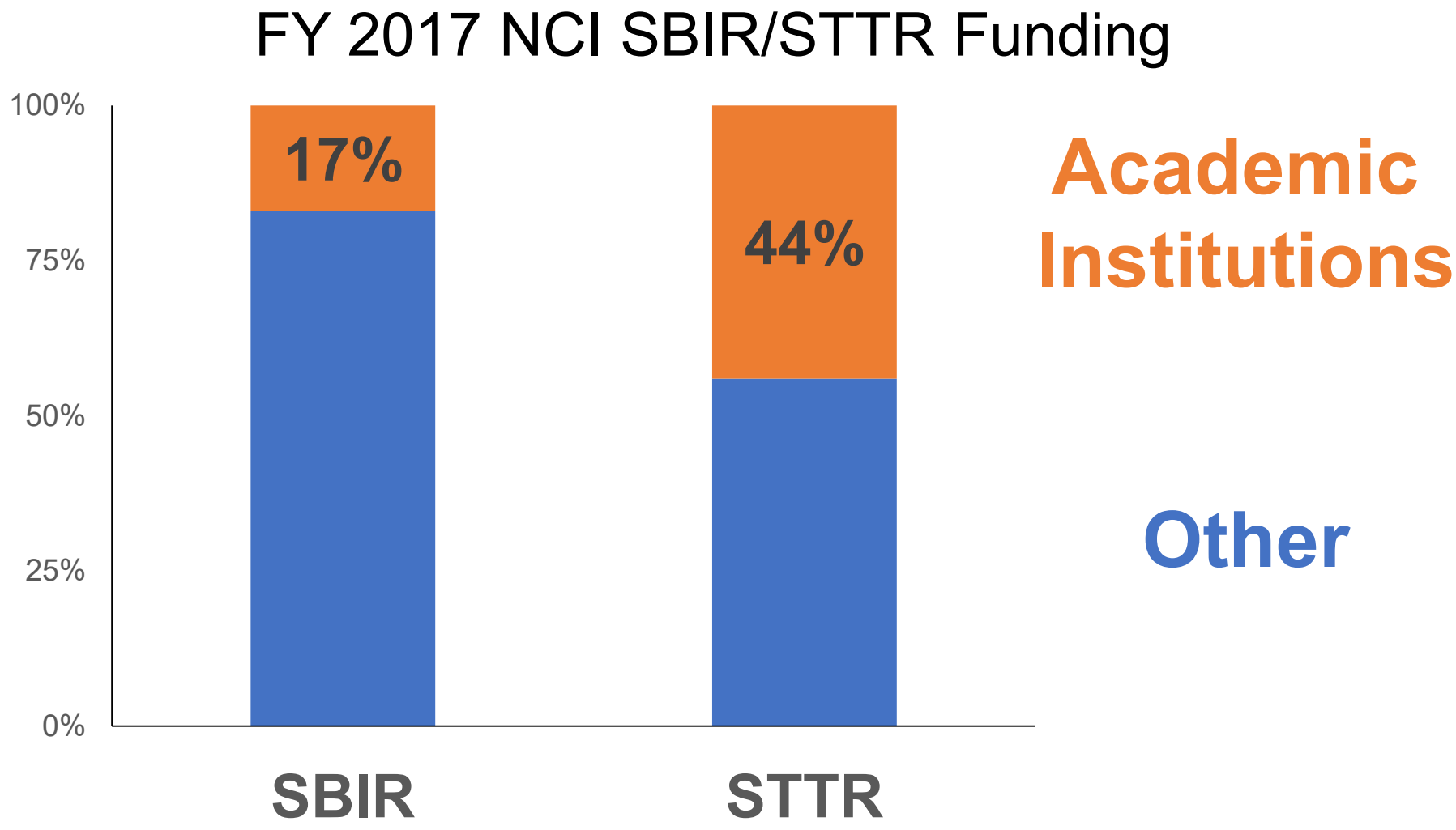
5. Are the assistance programs offered by the SBIR Development Center effective? Should the NCI consider new programs?

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?



6. What are the best ways for the NCI to support academics who are interested in using the SBIR program to commercialize technologies?

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?

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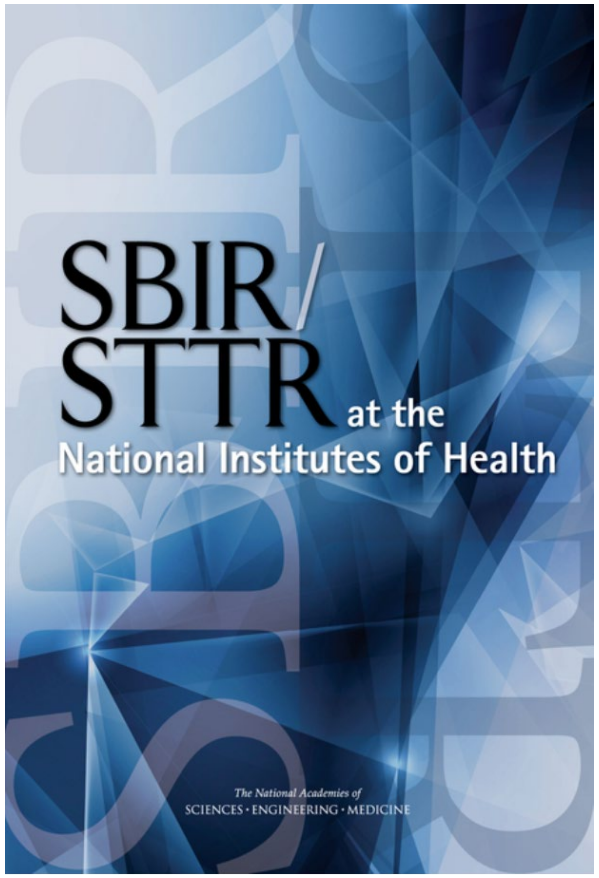
WORKING GROUP RECOMMENDATIONS

- 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?

2015 Report



SBIR/STTR FUNDING

NCI SBIR Monitoring and Evaluation

OUTCOME

IMPACT

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

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- 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”

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Return on Investment
2018 Economic Impact Study

“Return On Investment”

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$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

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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

Basic Economic Questions

- ✓ Total sales of new products and services (including R&D) related to NCI SBIR/STTR-developed technology?
- ✓ Other sales (licensing income, sales by licensees or spin-out companies)?
- ✓ Other economic impacts (outside investments in company, new company creation, sale of company)?

Data Collected on 91% of Companies

Reasons for High Response Rate

- ✓ Purpose and value of study clearly communicated
- ✓ Official letter from NCI SBIR director
- ✓ Pledged confidentiality
- ✓ Extensive research to find contacts
- ✓ Concise survey
- ✓ Persistent researchers

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

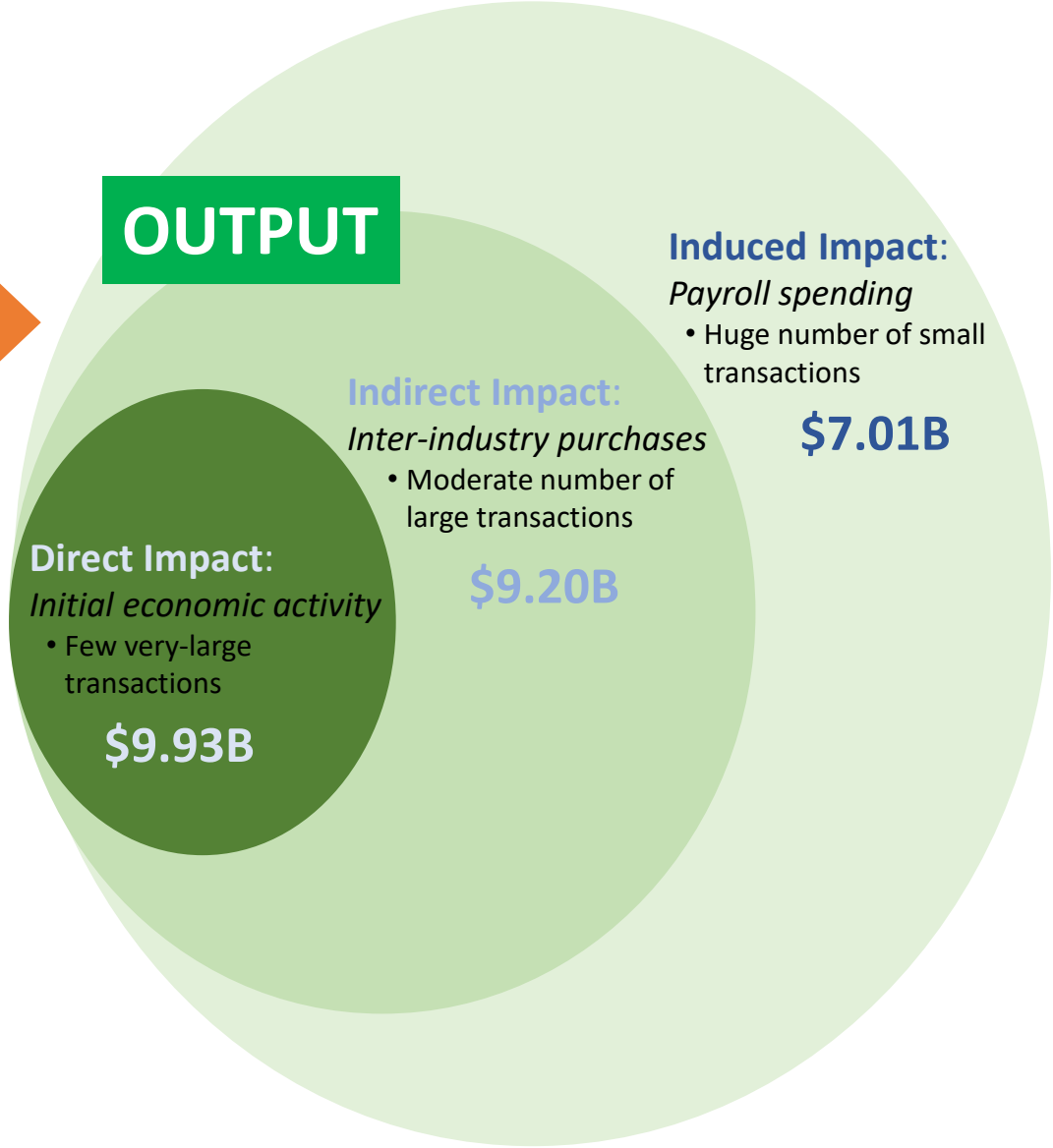
IMPLAN

An Input/Output model of economic impact

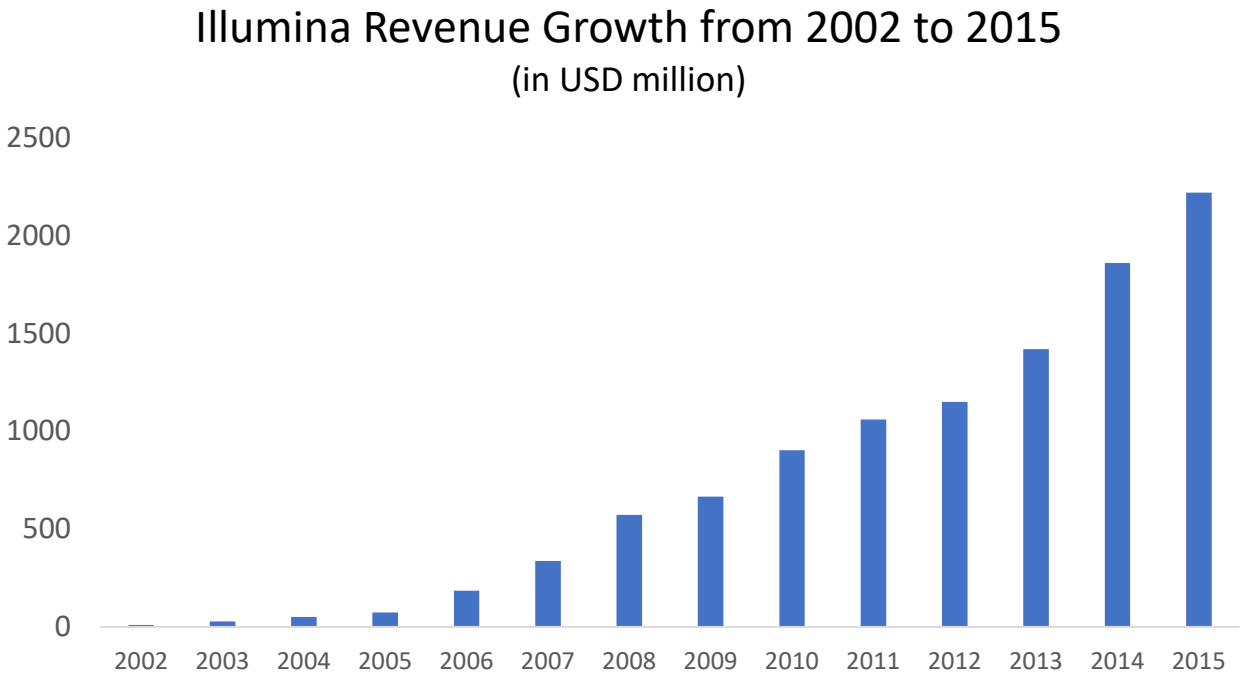
Uses US Dept. of Commerce data to model how money going into a specific sector affects the economy.

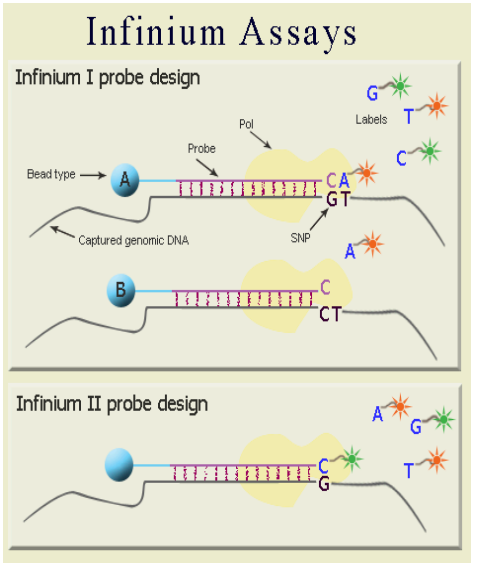
- $$ value for each product assigned to 1 of 536 sectors
- Each sector has a distinct multiplier
- Sectors include:
  - Surgical and medical instrument manufacturing
  - Pharmaceuticals

OUTPUT



Case: Illumina, Inc.





Infinium - $3.5B Sales

Infinium genotyping used for:

- All of Us Research Program (NIH)
- 23 & Me
- Ancestry.com
- Basic and Clinical Research
- Agriculture Industry

"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

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SBIR Funding: Naviscan 1994–2005; Gamma Medica 2007–2011

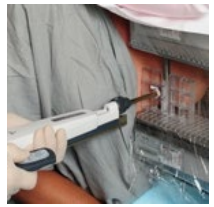
Proof of Concept	PROTOTYPE	CLINICAL EVALUATION	FDA APPROVAL

Solo II™ High-Resolution Breast PET Scanner

(2003)

First clinical dedicated breast PET scanner

Stereo Navigator



(2008)

PEM-guided biopsy system

Gamma Medica LumaGEM®

(2011)

Award-winning Molecular Breast Imaging Technology

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.

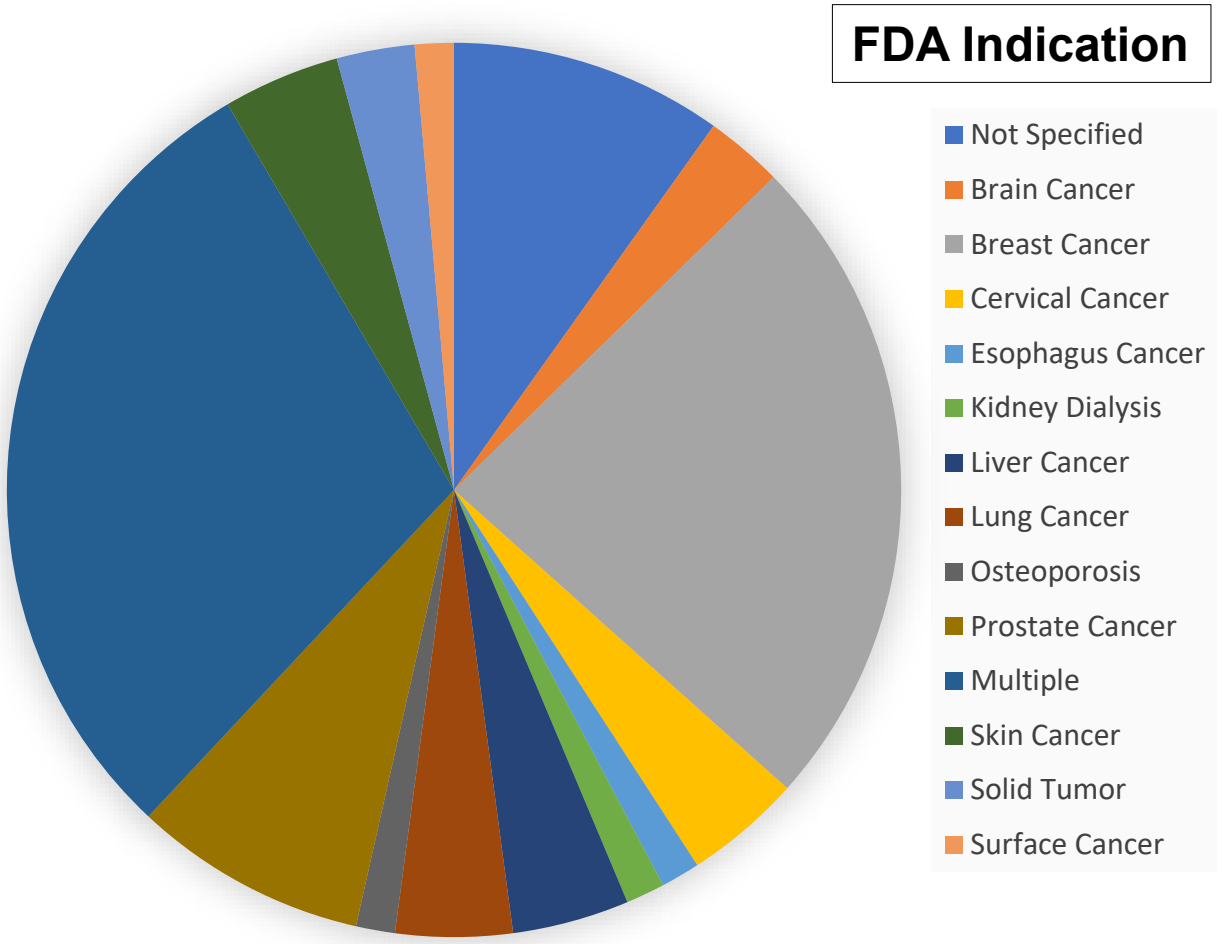
"The SBIR program was instrumental in funding the company from an early developmental stage which might have seemed a bit too risky for most venture capital groups….Naviscan's SBIR-funded research helped us to get through the early phase of the clinical trials required for FDA-clearance, which was opportunistically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



Patient Impact

247 commercially available products today that were supported by NCI SBIR/STTR awards between 1998 - 2010

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