National Cancer Advisory Board Ad Hoc Working Group Report of the National Cancer Institute Small Business Innovation Research Program

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National Cancer Institute
National Cancer Advisory Board

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Table of Contents

Executive Summary

The Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Program at the National Cancer Institute (NCI) is very strong and supports the development, translation, and commercialization of novel therapeutics, devices, diagnostics, and processes that are aimed at reducing the burden of cancer. There is strong centralized management by the NCI team, and there is good flexibility in the program. The SBIR/STTR funding is a critical element of the early-stage startup ecosystem. NCI SBIR offers entrepreneurship training programs and also provides critical links to investors and other commercialization and market services. The NCI staff also provides outreach and assistance programs to improve the quality of SBIR grants and to reach underserved populations and geographic areas. Additional analyses of the strengths of the program are highlighted below.

- Retrospective economic impact analysis of NCI SBIR/STTR Phase II grants from 1998-2010 indicates that there is a significant and substantial rate of commercialization, with 247 products commercialized out of 690 Phase II grants. Sales of products and services associated with these grants were estimated at $9.1B, and over 107,000 jobs were created. Total economic activity was valued at $26.2B.
- Many of the projects are highly innovative and feature disruptive technologies- approximately 65% of projects target innovative treatment and diagnostic options.
- There is significant leverage of the National Institutes of Health (NIH) funds- $787M in NCI SBIR funding leveraged $4.26B in outside investments and the acquisition of 101 companies was valued at $21.6B.
- SBIR and STTR funding supports the mission of NCI directly via grants, contracts, and targeted solicitations.
- The grants process is highly competitive, with funding rates that range between 10-15% for Phase I grants and 20-25% for Phase II. The peer-reviewed process and the non-dilutive funding substantially de-risk innovative, early-stage technologies.
- Analysis of specific case studies underscores the impact and importance of the SBIR/STTR program, and clearly shows how specific technologies are affecting the cancer burden.

Several opportunities for enhancing the SBIR/STTR Program at NCI have been identified and are primarily in the areas of process improvement and enhancing diversity among applicants. There is a continued need to reach out to underrepresented minorities and women-owned businesses. These underrepresented groups should also be recruited onto peer review panels and programmatic committees. Outreach programs and application assistance programs should be continued and expanded as needed, and should continue to focus on developing SBIR/STTR opportunities in geographically diverse areas. Other opportunities for enhancement include:

- SBIR/STTR peer-review panels in the NIH Center for Scientific Review and NCI Special Emphasis Panels should include individuals with strong backgrounds in commercial

development and clinical translation. Criteria for SBIR and STTR reviews should include a focus on innovation and commercial potential.

- Funding gaps between Phase I and Phase II should be minimized and the overall time between grant submission and funding should be reduced, with a goal of 7 months.
- Additional information should be collected from companies at time-of-award to allow the development of a robust set of leading and trailing metrics.
- New programs can be developed to address specific needs- examples include a Phase 0 "concept" grant to promote disruptive technology, programs to link SBIR grantees with the United States (U.S.) Food and Drug Administration (FDA) programs, and peer-to-peer mentoring.
- Coordination of SBIR projects with internal NCI programs such as NExT and the Technology Transfer Center can be enhanced.
- There is a need to educate both intramural and extramural academic investigators about the opportunities for SBIR/STTR-sponsored projects, and to develop postdoctoral programs to explore this opportunity.

The NCI SBIR/STTR program is meeting all its statutory goals but enhancements can be made in the area of diversity recruitment.

- *Stimulate technological innovation*: Analysis indicates that the NCI programs are leading to the development of cutting-edge technology in a wide range of areas. These technologies are having significant health impacts and are changing paradigms for the treatment, diagnosis, and prognosis for many different types of cancers.
- *Use small businesses to meet federal research and development (R&D) needs*: NCI uses targeted contracts and funding announcements to enhance the federal R&D landscape.
- *Increase private sector commercialization of innovations derived from federal R&D, thereby increasing competition, productivity, and economic growth*: The program has shown outstanding strength in this area. Econometric analysis has underscored the overall economic impact, and this type of analysis should be performed at five-year intervals.
- *Foster and encourage participation by socially and economically disadvantaged small businesses and by women-owned small businesses in technological innovation*: The NCI and NIH are using outreach and application assistance programs to encourage applicants. This should continue, and underrepresented individuals should serve on SBIR/STTR review and program committees. This area will demand continued efforts and practical methods to understand the many factors which contribute to a low rate of participation.
- *The statutory purpose of STTRs is to stimulate partnerships of ideas and technologies between innovative small business concerns and research institutions through federally funded research or R&D*: Although considerably smaller than the SBIR program, the STTR grants are serving their intended purposes by promoting exchange between research and business concerns.

Charge to the Ad Hoc Working Group

At its November 2017 meeting, the National Cancer Advisory Board (NCAB) of the NCI voted to create an ad hoc Working Group to evaluate the NCI SBIR program and develop recommendations for how the program can be enhanced going forward. As part of his charge to the Working Group, Dr. Sharpless requested that the questions below be considered.

1. What is the best way to review SBIR/STTR applications within the NIH peer review environment/process? How to get better quality of external reviewers, especially with regards to industry expertise? How to reduce time to decision-making with regards to funding?
2. Are award sizes for the different phases of funding for SBIR/STTR appropriate? If not, what sort of adjustments should be made?
3. SBIR/STTR predominantly fund life science companies interested in three areas (therapeutics, devices, and diagnostics). The path to commercialization is very different in each of these areas. On a portfolio wide basis, is SBIR funding too much or too little in each area?
4. How should NCI assure that SBIR/STTR programs fund life sciences startups with geographic diversity, and with gender/ethnic diversity in terms of leadership?
5. The NCI SBIR Development Center offers a number of programs to provide resources that small life sciences companies need in addition to funding (e.g., I-Corps, Investor Initiatives, applicant advice). Are these programs of value? Are there additional resources or services that NCI should consider providing?
6. What are the best ways for the NCI to support academic innovators who are interested in utilizing the SBIR program to commercialize their technologies? Are there ways the SBIR program could better work with extramural awardees (e.g., the Cancer Centers, SPOREs, NCTN)?
7. Are there ways that the NCI SBIR program could better partner with the NCI intramural program (including the Clinical Center), the Frederick National Lab for Cancer Research, and/or other NCI-managed initiatives that do not involve extramural funding (e.g., NExT program)?
8. The NCI SBIR program has developed a set of performance and commercialization metrics to evaluate the program. Many of these metrics are milestones that a company would reach in out-years after the award, making a robust collection system difficult. Are there any specialized or additional metrics that the NCI SBIR program should incorporate? Are there any program analysis best practices or models that the NCI SBIR program should incorporate?

Top Recommendations from the Working Group

Based on careful analysis and the consideration of a range of options, the NCAB SBIR Working Group recommends that NCI move to implement the following top recommendations below. Each recommendation is justified and discussed in more detail in the following sections on Working Group Topic Areas.

Portfolio Balance and Award Sizes

- Create a new high-risk, high-reward SBIR Phase 0 "Concept" Grant ($100-$150K) featuring a rapid review process. Concept Grants are expected to be short applications where the concept is judged on innovation, significance, and perceived feasibility. Preliminary data will not be required. These awards should enable key experiments that provide the foundation for a follow-on, high-impact Phase I grant application. Concept Grants could be used as targeted funding mechanisms to support disruptive technologies and other high-risk/high-reward projects that the private sector might be reluctant to fund at an early stage. We recommend a set aside of about $1M, funding perhaps 10 projects in the first year. This proposal received strong endorsement from all the members of the Working Group.
- Initiate proactive use of supplements as a tool for rewarding grantees that have made substantial progress towards their stated milestones. Supplements would be utilized to provide additional funds to awardees to help them reach the next critical value inflection point in a timely manner. The supplement amounts recommended are up to 50% of the base award for Phase I SBIR and up to 25% of the base award for Phase II. Supplements will be reviewed by the SBIR program internally to ensure speed and efficiency.
- Increase award size for SBIR Phase I from $300K to $400K to keep up with the increasing costs associated with achieving the milestones that are typically performed in Phase I. This would bring NCI more in line with award sizes for Phase I grants at other Institutes and Centers (ICs) including the National Institute of Neurological Disorders and Stroke.

Peer Review

- Strongly support and prioritize (at the NIH level) the implementation of the recommendations of the NIH SBIR Peer Review Improvement Committee including increasing the recruitment of reviewers with product and business development expertise, modifying standard review criteria to better fit SBIR/STTR, and adding a scoring criterion focused on the strength of the company's commercialization strategy for Phase II applications.
- In recognition of the accelerated timelines that small businesses often face, the NCI SBIR Development Center has taken several steps to accelerate the receipt-to-award time for grant applications, from an average of 12 months in 2013 to an average of 7.6 months in

2017. The Working Group believes that a target goal of an average of 7 months is reasonable and appropriate due to the numerous steps required in the funding process.

- Reduce the average time-to-award for SBIR contracts from 11 to 9 months. The Phase II Request for Proposal (RFP) could be due no more than 30 days after the Phase I RFP, which should enable joint Phase I/II peer review meetings to be held approximately three months after the receipt of Phase I applications and would reduce the current timeline by two months. Also, Contracting Officials should communicate with offerors whose proposals were deemed technically unacceptable as soon as possible after review so they can seek other funding opportunities.

Resources to Support SBIR Awardees in Addition to Funding

- Initiate an FDA regulatory assistance program based on a survey of NCI SBIR funded companies to identify regulatory pain points. Examples of potential assistance include educational webinars in collaboration with the FDA, resources web page of applicable FDA guidances, and facilitated interactions between FDA and SBIR companies.
- Establish a peer-to-peer mentoring program with a goal to connect founders/CEOs of NCI SBIR funded startups so they can share lessons learned, best practices, advise fellow founders/CEOs on real-life startup issues, and provide an overall support network.

Resources to Support Academic Investigators Seeking to Commercialize Their Innovations

- Connect academic investigators with NCI SBIR Investor Initiatives and other SBIR/STTR training programs. Promote the STTR program, in particular, as a vehicle for academics to collaborate with small businesses and spin-out companies.
    - Establish a Web portal of SBIR/STTR resources that can be made available to promising academic investigators.
    - Create regional NCI I-Corps entrepreneurship training programs to promote participation of academic investigators in regional I-Corps programs. Foster and encourage greater participation among STTR awardees in the I-Corps program.
    - Identify promising NCI funded academic projects and invite them to present to groups of investors at events convened by NCI SBIR.
- Create and disseminate an online “educational portfolio” to provide academics and technology transfer offices with resources to overcome challenges in commercializing technologies that originate in academia.

Partnering with Other NCI Programs

- Establish a postdoctoral training program in grantsmanship, entrepreneurship, and tech transfer in collaboration with the NCI Technology Transfer Center.

- Establish an SBIR Development Center-NCI Developmental Therapeutics Program (DTP) Collaboration, and an SBIR Administrative Supplement Program to increase SBIR competitiveness in the NExT program. The NExT program offers drug development services on a peer-reviewed application basis to the cancer research community.

Metrics

- Due to the lessons learned from the 2018 Economic Impact study on the NCI SBIR program, we are recommending that a similar report be commissioned every 5 years by a third party. The report will evaluate the economic impact of the program on the U.S. economy and identify any health and well-being impacts of SBIR-funded technologies on cancer patients and their caregivers.
- Implement an intake survey to establish metrics baselines for SBIR awardees. The survey should include:
    - A clear identification of the intended product.
    - Technology development metrics (e.g., development stage at the beginning of the project).
    - Commercialization milestone metrics (e.g., licensed patents, existing regulatory filings).
    - Business/financial metrics (e.g., private funds raised at time of project initiation).
    - Leadership make-up metrics (in concert with the women/minority sub-group).

Diversity

- Implement a survey at time-of-award to collect metrics on the company founders, owners, and leaders. The diversity sub-group developed and implemented a survey as part of the Working Group activities. The results of this survey proved more informative than the currently available data at NIH. Therefore, this recommendation is to implement a similar survey for all new small businesses at time-of-award including:
    - Women and minority founders.
    - Women and minority owners, in ownership categories that are relevant to the biotechnology industry (i.e., >51%, 25-50%, 10-25%, 1-10%, >0% but less than 1%, and 0%).
    - Women and minority leadership in the company, at the executive-level (C- and president-level), and day to day decision makers not in leadership.
    - Women and minority participation on the company advisory boards.
- Increase participation by women and minorities on SBIR review panels.

Overview of NCI SBIR Program

SBIR/STTR Programs: Mission and Goals

The Federal Small Business Innovation Research (SBIR) program was first enacted by the U.S. Congress in 1982, and it requires federal agencies with extramural R&D budgets that exceed $100 million to set-aside 3.2% (FY 2019) to fund small business awards. The Congressionally-mandated goals of the SBIR program are to stimulate technological innovation, meet federal R&D needs, foster and encourage participation in innovation and entrepreneurship by women and socially or economically disadvantaged individuals, and increase private-sector commercialization of innovations derived from federal R&D funding. In 1992, the Congress also established the Small Business Technology Transfer (STTR) program, which requires agencies with extramural R&D budgets exceeding $1 billion to set-aside an additional 0.45% (FY 2019) to support STTR awards at small businesses. The major distinguishing feature of the STTR program is that projects must involve a cooperative R&D arrangement between small businesses and research institutions. The NIH participates in both SBIR and STTR, and the combined funding from these programs provides one of the largest sources of early stage financing for U.S.-based small businesses focused on developing new biomedical products and related technologies.

At the NCI, the SBIR and STTR programs support a large portfolio of small business awards that align with the broader goals of the NCI. The mission of the NCI SBIR program is to serve as the primary NCI resource for commercial development of high-impact biomedical technologies that prevent, diagnose, and treat cancer-related diseases. NCI SBIR supports early-stage R&D at small business concerns (SBCs) across the U.S. to develop innovative technologies that advance cancer research, detection, diagnosis, treatment, and prevention. Importantly, the NCI SBIR/STTR programs play a frontline role in reducing the burden of cancer by supporting the early-stage development of new products and services that directly serve patients. In FY 2018, the NCI SBIR/STTR programs provided approximately $167 million in funding to U.S. small businesses, supporting a diverse portfolio of projects focused on cancer therapeutics, diagnostics, research tools, and other cancer-related technologies.

As a unique investor in the healthcare ecosystem, the NCI SBIR Development Center (the "Center") has identified three strategic objectives to help guide NCI's efforts in funding early-stage technology development:

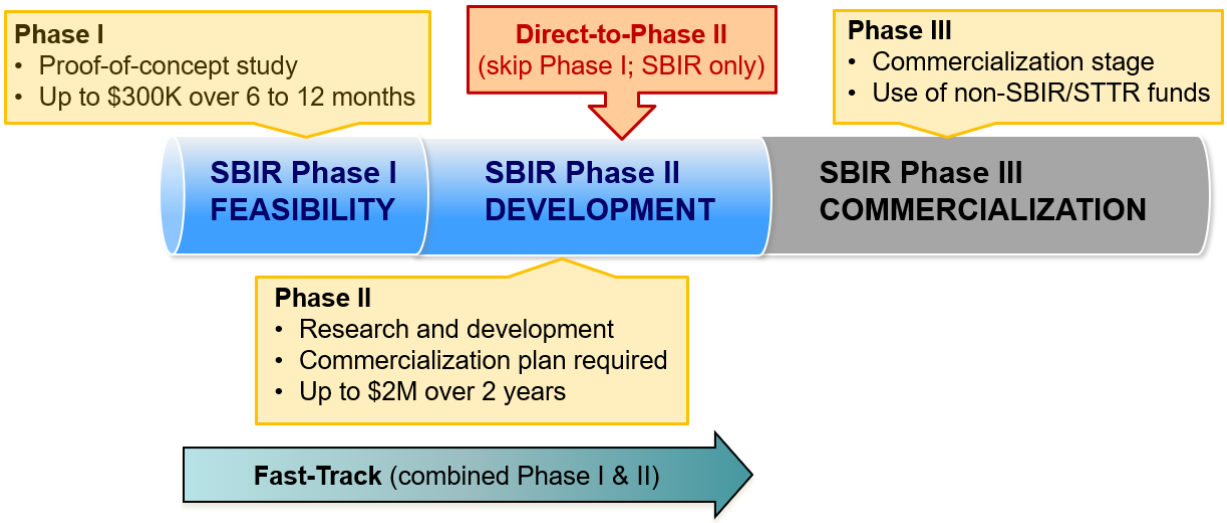
1. Take calculated risks to fund cancer-focused translational research projects with the potential to become disruptive innovations;
2. Fund projects in "gap" areas that are not being adequately addressed by industry, in order to develop products for neglected cancers and patient populations, as well as underserved cancer markets; and
3. Provide resources and training to support portfolio companies and prospective applicants, including help with developing and accessing the entrepreneurial skills needed to advance cancer projects and create value.

While most NIH funding mechanisms are focused on conducting basic research to generate new knowledge, this is not the objective of the SBIR/STTR programs; therefore, an important aspirational goal of the Center is to support a diverse portfolio of high-impact, cancer-focused translational research projects, and to advance all projects to a critical value inflection point on the path to commercialization.

Three Phases of Funding in Federal SBIR/STTR Programs, Including at NCI the Phase IIB Bridge Award

The structure of the Federal SBIR and STTR programs includes three phases (I, II, III) of funding as shown in Figure 1.

Figure 1. Three Phases of Funding for Federal SBIR and STTR Programs



First-time SBC applicants can apply for a Phase I, Direct-to-Phase II (SBIR only), or Fast-Track grant. The Direct-to-Phase II option, exclusively offered for the SBIR program, allows companies without a prior Phase I award to apply directly for Phase II funding support if they have completed the equivalent of Phase I work previously. The Fast-Track option (intended for more advanced projects) allows SBCs to apply for both Phase I and Phase II funding simultaneously to eliminate the funding gap between Phase I and II. SBCs that have completed a Phase I project are eligible to apply for Phase II funding.

The NCI SBIR Phase IIB Bridge Award program was introduced in 2009 to help promising small businesses address the funding gap between the end of the Phase II award and commercialization, commonly known as the “Valley of Death”. This funding gap often arises for SBCs due to the high cost and length of time required to perform key activities necessary for market entry (e.g., IND-enabling studies, manufacturing, and the generation of clinical trial safety and efficacy data). Companies that are developing cancer-related technologies with a Phase II SBIR or STTR award from any federal agency are eligible to apply for the Phase IIB Bridge Award of up to $4 million. The Phase IIB Bridge Award provides competitive preference and funding priority to applicants that can secure non-federal matching funds (1:1 minimum).

This program is used to incentivize partnerships between successful Phase II small businesses and private investors at a critical stage of development.

In order to measure the impact of the NCI SBIR Phase IIB Bridge Award program on SBCs that received these awards from 2009-2016, this program was independently evaluated outside of NCI in 2017 by an Evaluation Team that included private sector experts and NIH staff. The Evaluation Team found that:

- NCI has funded $51 million in Bridge projects (21 awards) and they, in turn, were able to raise more than $220 million in private capital matching funds. This translates to, on average, Bridge awardees raising more than $4 of private funding per $1 granted from the NCI.
- The program has been successful in incentivizing private investment in SBIR-funded early stage projects since awardees' projects have been vetted by NIH peer review and have also been de-risked by NIH funding.
- Having this award as an option is important for small businesses who are often at a fragile stage of growth, and most SBCs found that applying for this award had a positive impact on investors as a context in which to raise private matching funds.
- Ten out of the 21 companies funded through the Bridge Award program have successfully commercialized their technologies.

Overall, the Evaluation Team found the Phase IIB Bridge Award program met its goal of accelerating the commercialization of SBIR-funded projects and they strongly supported continuation of the program. As a final note, the NCI Phase IIB Bridge Award model first implemented in 2009 was subsequently adopted by two other institutes at NIH- the National Heart, Lung, and Blood Institute and National Institute of Neurological Disorders and Stroke.

Funding Mechanisms: Grants and Contracts

The NCI SBIR program oversees a portfolio of more than 400 active projects at any given time. The majority of these projects are funded under SBIR and STTR grants (mostly investigator-initiated grants, and to a lesser extent grants funded under targeted Funding Opportunity Announcements [FOAs] and Request for Applications [RFAs]). NCI SBIR/STTR grant funding is primarily awarded under the NIH Omnibus SBIR and STTR Grant Solicitations with three receipt dates every year. Omnibus Solicitations are NIH-wide funding opportunities that are broad in scope and welcome investigator-initiated grant applications on topics related to the NIH's mission. Grant applications are reviewed by the NIH Center for Scientific Review in SBIR/STTR-only peer review panels and receive an overall impact score based on five review criteria: significance, investigator(s), innovation, approach, and environment. They are not percentiled by NIH (as R01s are) owing to the small number of applications reviewed in one study section in one round.

In addition to grants, SBIR contracts are used to support targeted research on NCI-initiated topics that are a high priority to NCI and have strong commercial potential, and contract topics are published once per year. NCI also utilizes the SBIR contract mechanism to provide funding to a greater number of technology market areas including underserved markets. SBIR contracts use the same funding phases as described above for grants (though the Phase IIB is not used in contracts), and they represent a minority of the portfolio. Approximately 15-25% of NCI SBIR funding is awarded annually to SBCs through SBIR contracts. In contrast to investigator-initiated grant topics that are developed by SBCs, contract topics are defined by the NCI. To do this, each year the NCI SBIR staff collaborates with Divisions, Offices, and Centers across the NCI to develop contract topics in cancer-related areas of interest that cut across the NCI mission. SBIR contract topics are published once per year as part of an NIH-wide Omnibus SBIR Contract Solicitation, and SBIR contract proposals have only one receipt deadline every year. SBIR contract proposals are peer reviewed by the NCI Division of Extramural Activities in ad hoc expert peer review panels assembled for like topics, with a target of >50% of peer reviewers having industry experience. SBIR contract projects are more milestone-driven and subject to greater oversight by NCI SBIR staff than SBIR grant projects.

NCI SBIR Development Center: Management Model and Core Activities

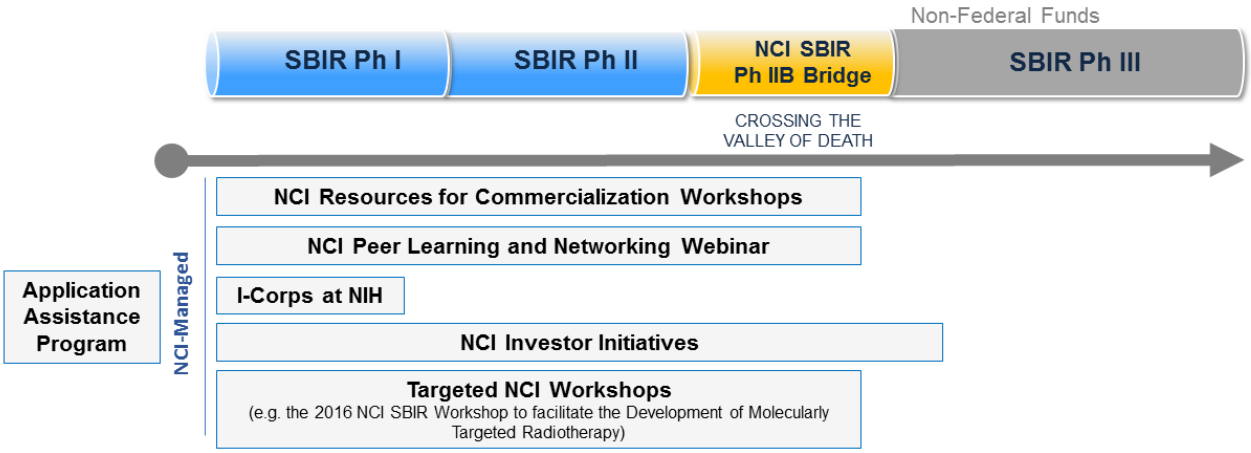
Most NIH ICs follow a distributed management model for the SBIR and STTR programs where Program Officers from across multiple staff Divisions oversee a few SBIR/STTR projects along with their primary responsibility of overseeing academic grant projects. While these Program Officers are experts in scientific research areas, they are not expected to have commercialization expertise. Furthermore, some ICs have separate SBIR Coordinators who are responsible for administering the SBIR and STTR programs, and answering SBC applicant questions, but they do not directly oversee active projects.

In contrast, the NCI SBIR program is managed centrally within an organizational unit called the NCI SBIR Development Center. In 2007, the Center was formed based on a centralized model for program management that focuses exclusively on commercially directed SBIR/STTR programs. The Center comprises 11 full-time Program Directors who collectively have a wide range of cancer research expertise, as well as knowledge of technology commercialization. While funding SBCs that are developing promising cancer-related projects is a key role of the Center, non-funding assistance is equally important to advance innovative technologies into the clinic and toward ultimate commercialization. NCI SBIR Program Directors are not only responsible for advising companies on their applications and overseeing both technical and commercial progress for active grants and contracts, they also facilitate interactions between awardees and potential investors to expedite commercial development. Due to their continuing involvement and understanding of an SBC's scientific and entrepreneurial requirements, the Program Directors are uniquely positioned to identify resources that may accelerate the commercialization efforts of their portfolio companies.

The centralized management approach has enabled the NCI to pioneer the development and offering to the SBC community of a range of SBIR/STTR program resources, including I-Corps™ at NIH, Investor Initiatives, biennial awardee workshops around federal resources for commercialization, and the aforementioned NCI Phase IIB Bridge Award. These resources are

specifically designed to help SBCs with technology development for commercialization. In addition, several of these programs have now been adopted by other NIH Institutes. Examples of these resources, organized by funding phase, are shown in Figure 2.

Figure 2. NCI SBIR Development Center Resources for Portfolio Companies



The core activities of the Center are as follows:

- Provide central oversight of all 400+ NCI-funded SBIR and STTR projects.
- Identify, develop, and manage targeted SBIR/STTR solicitations and SBIR contracts to seed emerging technology areas.
- Guide applicants in preparation of funding applications and resubmissions.
- Conduct more than 30 outreach events annually across the U.S. to raise awareness, solicit research funding applications from SBCs, and to seek out promising technologies.
- Provide entrepreneurial training programs such as I-Corps™ at NIH, workshops, and webinars.
- Facilitate connections between awardees and potential third-party investors/strategic partners to support leveraging of funding from other sources and the eventual transition to non-federal follow-on funding.

By providing funding and other resources to small businesses during pre-clinical and clinical development, the Center aims to increase the translation of innovative cancer-related research into technologies available for clinicians, patients, and their families. This work is in support of NCI's mission to improve the health of all people by reducing the burden of cancer.

Key Findings from the NCI SBIR Impact Study

In 2018, the NCI SBIR program commissioned an external evaluation of the program. There were three principle components of this evaluation: (1) evaluate the economic impact of the NCI SBIR program on the U.S. economy, (2) determine the critical role that SBIR funding played for moving technologies forward at the company, and (3) understand the current status of the technology. The evaluation was conducted with a test cohort of all NCI SBIR Phase II grant awards made between 1998-2010. Technologies funded after 2010 were not included in the evaluation due to the long commercialization time needed for biomedical technologies. This evaluation was the first to evaluate and model the economic impact of any SBIR program within the U.S. Department of Health and Human Services.

Economic Impact

This study was modeled after economic impact analyses of the SBIR programs for the U.S. Navy and the U.S. Air Force. The Navy and Air Force studies allowed analysts to refine their data collection system and demonstrate the wide use among federal agencies and the private sector to determine the economic impact of a program or industry. The results of the economic impact analysis are summarized in Table 1.

Table 1. The induced effects on the economy resulting from $787M in Phase II NCI SBIR awards granted between 1998-2010, and the subsequent sales of resulting technologies. *Note – columns may not tally due to rounding.*

	Description	**Amount in Millions (input)**	**Total Economic Output ($ Millions)**	**Employment (1998-2018)**	**Tax Revenue ($ Millions)**
Tier 1: Awards	All Phase II SBIR awards granted between 1998-2010	$787	$1,980	9,908	Not modeled
Tier 2: Sales	Sales figures reported by responding awardees	$9,144.4	$24,160	98,011	Not modeled
Tier 3: Total	Sum of award dollars and sales figures	$9,960.6	$26,150	107,918	$2,930

Technology Development

Due to the mission-driven focus of the NCI, it is critical that evaluations include the impact of NCI SBIR funding on technologies that will ultimately affect the lives of cancer patients. We therefore included a series of high-level questions focused on technology development.

According to interview respondents:

- 89% stated that the NCI SBIR program provided funding at a pivotal moment for the small business.
- 63% stated that a university was involved in the development of the technology, demonstrating the close relationship between SBIR-facilitated development and commercialization of inventions out of U.S. research institutions.
- 247 NCI SBIR-funded products were commercialized out of 690 funded Phase II SBIR grant awards.
- 110 NCI SBIR-funded products are still in development.
- 65% of the awards funded the development of a new treatment for a group of patients who lacked a treatment option.

IMPLAN Economic Model

IMPLAN is used by several industry organizations, such as BIO and AdvaMED, to determine the effect of their industry on the economy. IMPLAN is also used by several federal agencies, Defense, Agriculture, Energy, etc. to evaluate the effect of federal programs on the U.S. economy. IMPLAN draws on a mathematical input-output framework originally developed by Wassily Leontief, the 1973 Nobel laureate in economics, to study the flow of money through a regional economy. IMPLAN assumes fixed relationships between producers and their suppliers, based on demand, and that inter-industry relationships within a given region's economy largely determine how that economy responds to change. Increases in demand for a certain product or service (for example, sales of a new NCI SBIR-developed medical device) cause a multiplier effect- a series of ripples through the economy. This increased demand affects the producer of the product, the producer's employees, the producer's suppliers, the supplier's employees, and others, ultimately generating a total impact on the economy that significantly exceeds the initial change in demand.

For example, MedTech Corporation used its NCI SBIR Phase II funding to develop improved endoscopic ultrasound systems. It now manufactures and sells these systems to the medical industry worldwide. This requires MedTech to hire factory workers, who subsequently spend their payroll checks on groceries and other goods. In addition, MedTech purchases industrial machines, tools, electronic components, supplies, and packaging materials from other companies, which also employ workers who purchase groceries and other goods, and so on.

Non-IMPLAN Modeled Outcomes

As a result of the study design, the economic survey captured additional data that could not be modeled in IMPLAN but had a positive effect on the economy. The IMPLAN model uses activities as the base for its algorithm and there are some monetary transfers that cannot be associated with a specific activity. For example, venture capital investment may be tied to

specific activities such as R&D, but it may also be wealth transfer for equity, making it impossible to appropriately model. The outcomes of NCI SBIR-funded technologies that were not included in the IMPLAN model of economic impact are:

- **Total outside investment funding:** $4.26 billion
- **Number of companies that were acquired:** 101
- **Total acquisition value of companies acquired:** $21.63 billion
- **Number of technologies licensed to other companies:** 103
- **Number of spin-out companies created:** 45

NCI SBIR Study Design

Data Collection. The data for the 2018 NCI SBIR Impact study were collected by a series of telephone interviews. **There was a 91% response rate to the survey (407 companies / 444 companies contacted).** Nearly all interview respondents had the position of project PI, C-level executive, or President-level executive. In some cases, marketing managers were interviewed as they were deemed to have the most knowledge about product sales. Interviewees were asked a series of questions about monetary transfers, including: sales (by primary funded entity, spin-out company, or sub-licensee), follow-on research funding, investment funding, company acquisitions, and new company creation around the technology. **In total, 53% of respondents stated that their technology had generated some "sales" after the Phase II NCI SBIR award.** A breakdown of sales categories is summarized in Table 2.

Table 2. Product sales categories and amount of sales reported by 648 interview respondents. *Note – columns may not tally due to rounding.*

Sales Category	**Total Sales ($ Millions)**	**Percent of Total**
Commercial Product/Services Sales by the SBIR/STTR Recipient	$7,996.6	87
Sales by Licensees	$140.2	2
Sales by Spin-Out Companies	$56.3	1
Royalties from Licensees	$29.2	0.3
Follow-on R&D Awards	$957.3	10
TOTAL	**$9144.4**	**100**

Economic Data Processing. Monetary data that were collected via telephone interview were sorted according to the activity and aligned with industry classification codes, NAICS, developed by the Department of Commerce to generate economic data.

NAICS is the U.S. government's standard industry classification system. It is a comprehensive production-oriented system that groups companies and divisions of companies into industries based on the business activities in which they are primarily engaged. NAICS recognizes 1,057 different industrial activities and assigns a unique code to each. NAICS codes can be found at the U.S. Census Bureau's NAICS code website (*http://www.census.gov/eos/www/naics/*).

NCI SBIR award dollars were assigned to one NAICS code, 541715, Research and Development in the Physical, Engineering, and Life Sciences. Monetary data from follow-on R&D fundraising and product sales were categorized into 34 additional NAICS codes.

IMPLAN Modeling. IMPLAN used the economic data subdivided into NAICS codes to predict the effect of SBIR funds, additional follow-on funding, and product sales on the economy. IMPLAN reported the effect at four levels:

Direct Effect: The economic output generated by the company

Indirect Effect: The economic output generated by the supply chain companies

Induced Effect: The economic output generated by the downstream ripple effect of economic events enabled by both the company and its supply chain companies (e.g. the services provided to the company and supply chain employees)

Total Effect: The overall effect, including multipliers, on the U.S. economy

The total effect is included here. A more comprehensive report includes data in additional detail.

Technology Development Analysis. Unique to the NCI study was the inclusion of a series of technology development questions including: current development stage, regulatory approval status, intended use, and university involvement. Narrative responses were analyzed for common themes using text mining.

Working Group Topic Areas

Topic 1: Improving Peer Review

Background

The NCI funds investigator-initiated SBIR and STTR grant awards primarily through two parent FOAs called the Omnibus solicitations. Each year the NCI receives approximately 1200 grant applications under these FOAs, and the applications are assigned to peer review panels convened by the NIH Center for Scientific Review (CSR). Small business applicants and other external stakeholders have raised concerns about the suitability of the standard NIH review process for SBIR/STTR applications. An evaluation of the NIH SBIR program conducted by the National Academy of Sciences (NAS) highlighted the peer review system as one area where improvement is needed.

In response to the NAS recommendation, the NIH convened an SBIR Peer Review Improvement Committee in 2016. Three subcommittees were established including a Phase I Subcommittee, a Phase II Subcommittee, and a Finding Reviewers Subcommittee. The Phase I and Phase II Subcommittees were tasked with identifying strategies to optimize the review processes for each Phase. The Finding Reviewer Subcommittee was tasked with identifying strategies for improving the composition of small business review panels. A report containing the committee recommendations has been finalized and is currently under review by several trans-NIH committees and working groups including the NIH Extramural Program Management Committee (EPMC) and the NIH Extramural Activities Working Group (EAWG). The report includes the following recommendations:

- Modify the definitions of the five standard NIH review criteria to better fit SBIR/STTR, including major changes to the innovation criterion to ensure more focus on the value proposition and IP, and less focus on the use of innovative methods.
- Increase efforts on the recruitment of reviewers with product development and commercialization expertise. Develop an NIH-wide database of reviewers with commercialization expertise and set a minimum target percentage of panel members with such expertise.
- Strengthen training and sharing of best practices across CSR and IC review groups.
- Add a sixth scoring criterion focused on commercialization for Phase II applications. This criterion would include a focus on commercialization.

The recommendations above primarily address investigator-initiated SBIR and STTR grant applications that are reviewed by CSR. Grant awards funded under this process account for approximately 75% of the total NCI SBIR/STTR budget. The majority of the remaining 25% of the NCI SBIR/STTR budget is used to fund SBIR contract proposals that are received in response to targeted funding solicitations. Review criteria for SBIR contracts differ somewhat from grant review criteria. Contract review criteria are weighted by category and explicitly address commercialization factors, and proposals are reviewed by panels convened by the NCI

Division of Extramural Activities. When developing the recommendations that follow, the SBIR Working Group considered the differences in the peer review processes for SBIR/STTR grants versus SBIR contracts.

It is important to note that the peer review process represents a substantial portion of the time between when a grant application (or contract proposal) is received and when an award is made. The NCI recognizes that small businesses are often under pressure to make rapid progress; therefore, both CSR and the NCI have taken steps to accelerate the receipt-to-award time for grant applications, from an average of 12 months in 2013 to an average of 7.6 months in 2017. Over the same time span, the receipt-to-award time for contract proposals has remained fairly constant, averaging 11 months.

Working Group Assessment

1. The current peer review process is well-suited for the size and scale of the SBIR program.
2. The current balance of ~50% of the SBIR/STTR grants budget applied towards a scoring range in which programmatic discretion is used in making funding decisions is appropriate, and should not be increased both due to the concern of de-incentivizing review and scalability.
3. The SBIR-specific contract review criteria and weights are appropriate and include sufficient focus on commercialization.
4. The grant application time-to-award average of 7.6 months and goal of reaching an average of 7 months is reasonable and appropriate. Typically, the need to recruit an optimal review panel, provide reviewers sufficient preparation time, hold the review meetings, and develop the Summary Statements takes approximately four months. Once Summary Statements are available, program staff can review and make funding recommendations in about one month. Two months are then required to complete the processing of awards including review by the Office of Grants Administration (OGA), Office of Animal Laboratory Welfare (OLAW), Human Subjects concerns, etc.

Recommendations and Opportunities for Enhancement

1. The NIH Peer Review Committee's recommendations will significantly strengthen the peer review of SBIR/STTR proposals and should be given a high priority at the NIH level. Recommendations that were deemed critical include redefining the criteria definitions to better reflect SBIR/STTR, recruiting more reviewers with business expertise, including more ethnically and gender diverse reviewers, and adding a sixth scored criterion focused on commercialization strategy for Phase II. One concern with the NIH Peer Review Committee's recommendations is the increased focus on intellectual property (IP) in the recommended definition of the "Innovation" criterion. Analysis of individual patents/filings, IP portfolios, etc. is very complex and cannot be properly assessed without deep IP analysis that review committees are not resourced to do. The

SBIR Working Group recommends having applicants present their key patent filings and overall IP strategy at a high level only.

2. NCI should evaluate the feasibility of enabling companies to submit updated data at multiple points during the review and selection process for applications in the range of consideration. Small business timelines are accelerated, and it is very possible that new supporting data would have been generated in the time from application to review. A process to accept new data post-review for scores in the range of consideration should be formally implemented and advertised to ensure that applicants are aware of such an opportunity. Page limits for additional data to ensure scalability could be considered. It is important that this not result in an increase in the NCI SBIR budget percentage allotted to programmatic discretion.

3. NCI should expand the practice of inviting prospective grant applicants to submit pre-application summaries of their project ideas to enable program staff to advise applicants on the competitiveness of a planned proposal and provide guidance. Program staff should consider formalizing the current process of reviewing Specific Aims pages and adding the information to FOAs.

4. NCI should consider the issuance of an RFA with special review criteria to solicit proposals to develop technologies that address disruptive innovation. The solicitation could encourage highly innovative applications with little preliminary data. It should be made clear that the funding should cover one critical experiment to support an idea. Long-term, it will be important to evaluate the impact of the solicitation.

5. NCI should reduce the contract proposal receipt-to-award time to an average of nine months. The Phase II RFP could be due no more than 30 days after the Phase I RFP, which should enable joint Phase I/II peer review meetings to be held approximately three months after the receipt of Phase I applications and would reduce the current timeline by two months.

6. NCI Office of Acquisitions (OA) has taken steps to notify offerors of their proposal status as soon as such status is definite. Program staff confirm proposal status which occurs after the Science Review Officer (SRO) has provided peer review minutes (approximately two months post-review). It is recommended that SROs should notify the OA of the proposal scores and votes of technical acceptability within a few days of the peer review meeting. This would enable OA to notify offerors proposing technically unacceptable proposals within one week of the review meeting.

7. It is critical that NCI program staff attend/listen to the peer review of assigned applications. While this often occurs currently, efforts should be made to ensure attendance of program representatives at each review meeting.

Topics 2 and 3: Optimizing Award Sizes and Achieving Portfolio Balance

Background

The NCI SBIR/STTR program funds more than 400 ongoing Phase I and Phase II awards. Approximately 75% of these awards are selected from investigator-initiated applications and the remaining 25% of awards are funded under targeted solicitations for which the NCI defines the focus of the project. The technology sectors represented in the NCI SBIR/STTR grant portfolio, as well as the relative distribution of funding across these sectors, track closely with private sector investments across four broad technology areas (biopharma, diagnostics, devices, and health IT). By comparison, the projects funded under targeted NCI SBIR solicitations are more heavily focused on non-therapeutic areas (e.g., diagnostics, research tools, and Health IT including educational and survivorship tools) (Table 3). In most cases, targeted solicitations are used strategically to foster and encourage R&D in technical areas where the federal government is uniquely positioned to address market gaps and complement private sector funding.

Table 3. NCI SBIR/STTR portfolio by technology sector (percentage range from 2013-2017; average in parentheses)

	Biopharma	Diagnostics	Devices (including research tools)	Health IT (including epidemiological/educational tools)
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)

The budget limits established by Congress for SBIR/STTR awards are $225K (total costs) for Phase I and $1.5M (total costs) for Phase II; however, the NIH allows higher budgets for projects in certain technology areas deemed to be especially capital intensive (Table 4). Such project areas must be pre-approved by the U.S. Small Business Administration (SBA), and they are advertised in SBIR/STTR funding solicitations as "waiver topics." The NCI has identified waiver topics for several technologies including therapeutics, diagnostics, devices, and digital health tools. For applications submitted under waiver topics, the NCI has established budget limits of $300K (total costs) for Phase I and $2M (total costs) for Phase II. These hard caps were established by the NCI to strike a balance between spreading SBIR/STTR funds across several projects while also providing enough funding to ensure that individual projects are sufficiently resourced. If a project/technology falls under an approved waiver topic, then it is not necessary for a grant applicant to seek prior approval before requesting the NCI's higher budget limits. Importantly, while Congress has increased the SBIR and STTR set-asides substantially since 2011, the average award sizes have also increased during this same period.

Table 4. Current NCI SBIR/STTR award sizes

	Phase I	Phase II	Phase IIB
Statutory budget limits	$225K	$1.5M	$1.5M
NCI waiver topics (include many but not all cancer focused technologies)	$300K	$2M	$4M (at least 1:1 matching expected)

Working Group Assessment

After analyzing the data collected by the NCI SBIR program and scouting anecdotal data from small businesses, the Working Group believes there is a need to both enable larger award sizes for programs that merit additional investment and make it easier for the NCI to fund smaller awards with a faster review timetable. This approach is intended to "right size" awards (see details below).

The Working Group finds the current NCI portfolio distribution by sector to be appropriate and recommends the continued support of non-therapeutic projects using targeted SBIR/STTR funding mechanisms. The Working Group endorses the philosophy that every proposal should be evaluated on its own merit, irrespective of sector and without preconceived notions about where the next breakthrough in cancer treatments will emerge. The Working Group does not recommend establishing predefined percentages for awards in specific technology areas. If any one area begins to be underrepresented in the portfolio and in private funding landscape, then the SBIR staff can use targeted solicitations to reset the portfolio.

Recommendations and Opportunities for Enhancement

1. Reassess SBIR/STTR grant sizes and portfolio distribution at regular intervals. The average size and allocation of SBIR/STTR grants should be revisited every five years to ensure they are aligned with changes in experimental costs, capital availability, regulatory frameworks, cost to value inflection points, and reimbursement policy. During these reviews, NCI should track portfolio changes and analyze the private funding landscape. The Center is encouraged to continue reaching out to investors, patient advocates, and internal NCI experts to help define under-funded research areas.
2. Ensure that funded projects include value-creating milestones. Grants should fund the completion of meaningful project milestones that enable founders and scientists to both test their scientific hypotheses and create value needed to raise additional capital. One option to achieve this goal is to ensure that the development plan for each phase of an SBIR/STTR grant includes a value inflection point. Critical value inflection points are different for different technology areas. Value inflection points may be suggested in FOAs and should be evaluated during peer review and during the funding selection process for all Phase I, Phase II, and Phase IIB applications.
3. Increase the size of Phase I awards. Phase I awards should be increased to keep pace with the costs associated with achieving common technical feasibility and proof of concept

milestones. Milestones vary depending on the specific technology being addressed (e.g., therapeutics, diagnostics, and devices); therefore, "success" is defined differently for various technology areas. Based on an analysis of the average costs associated with achieving value creation across technologies, the Working Group recommends increasing the Phase I budget cap to $400K. While this increase may lower the total number of awards each year, this change is recommended to improve the overall rate of success for projects. The Working Group does not recommend any changes to the current Phase II and Phase IIB award sizes.

4. Expand the use of administrative supplements. The NCI should expand the use of administrative supplements for SBIR/STTR Phase I and Phase II projects to help companies respond to real-time challenges and achieve critical milestones. Program staff should be authorized to approve administrative supplements up to 50% of the parent award for Phase I and up to 25% of the parent award for Phase II. The NCI should consider setting aside a minimum portion of the SBIR/STTR budget (5%) to fund administrative supplements on an ongoing basis, and program staff should establish a streamlined process to rapidly identify and review projects that need additional resources. The NCI should track the outcomes for companies receiving administrative supplements during the first 1-2 years of this new initiative.

5. Establish an SBIR/STTR Concept Grant (Phase 0 award). The NCI should offer new Concept Grants (or Phase 0 awards) that are small in size ($100-$150K) and can be reviewed and funded rapidly (within six months). These awards should enable key experiments that provide the foundation for a follow-on, high-impact Phase I grant application. Concept Grants could be used as targeted funding mechanisms to support disruptive technologies and other high-risk/high-reward projects. The goal should be to de-risk projects to make them palatable for the private sector and/or better candidates for traditional SBIR/STTR grants. The NCI should obtain feedback from external life science investors on possible technology areas that might be pursued using Concept Grants. Applications should be very short, and the peer review should focus heavily on innovation. Preliminary data are not required. Other NCI initiatives that support technology commercialization (e.g., I-Corps) should be leveraged to help teams participating in the Concept Grant program.

6. Encourage projects that address underserved cancer markets. The NCI should use the omnibus solicitations and other targeted solicitations to more actively solicit projects that address gaps in private sector funding for urgently-needed cancer technologies. For example, this should include the development of biopharma agents for rare cancers, molecular diagnostics, and other products for underserved needs. The NCI should dedicate a substantial portion of its overall SBIR/STTR budget to support projects in these areas. The NCI should also consider partnering with rare disease cancer foundations, such as the Chordoma Foundation.

Topic 4: Enhancing Geographic and Gender/Ethnic Diversity

Background

Underrepresented SBCs were separated into two categories for analysis by the SBIR/STTR Working Group: 1) geographic diversity; and 2) women and minority diversity. While NIH captures data on geographic diversity as part of the grant application process, it was immediately apparent to the Working Group that there is very little data available on the participation of women and minorities in the NCI SBIR program as well as for other NIH SBIR programs. Therefore, as part of the Working Group activities, a survey was developed to gather new diversity data and compare to current benchmarks as a starting point from which to make recommendations. The survey included questions on the participation of women and underrepresented minorities within the company, in roles that are relevant to an industry setting. These roles included SBC founder, owner, day-to-day leader, and member of the Board of Directors. NIH does track diversity information on majority owners (women, plus socially and economically disadvantaged owners) when ownership is self-reported as part of the grant application process. However, to our knowledge, this is the first survey at NIH to ask SBIR/STTR recipients about the participation of women and underrepresented minorities in critical positions other than majority owner. The survey was sent to 539 NCI SBIR/STTR awardees funded 2013-2015, and 81 completed the survey. The results indicate that the actual involvement of women and underrepresented minorities as non-majority owners in funded SBCs is significant, but there is still room for improvement. For example, 13% of the SBCs (11 respondents) surveyed were solely founded by a woman or minority, 44% of surveyed SBCs had a female executive, and 17% had an executive who is an underrepresented minority. Execution of this survey allowed the Working Group to use a two-stage approach for recommendations in this important area: 1) gather current diversity data from SBCs and compare to current benchmarks; and 2) identify key areas for improvement, and set new diversity targets that were meaningful, reasonable, and achievable within the next 5 years.

Geographic diversity was defined by eligibility for the NIH Institutional Development Award (IDeA) program. The IDeA program, managed by the National Institute of General Medical Sciences, provides support to states or regions with historically low levels of NIH funding. The program was established in 1993 by Congress with the aim of broadening the geographic distribution of NIH funding, and current IDeA participants cover 23 states plus Puerto Rico.

The Federal SBIR program is mandated by Congress and has four statutory purposes (see Overview of NCI SBIR Program). In a 2015 review of the NIH SBIR/STTR programs by the NAS, the report concluded that the only statutory purpose not being satisfactorily addressed by the NIH was to foster and encourage participation by socially and economically disadvantaged small businesses (SDB), and by women-owned small businesses (WODB).

The federal definitions for WOSB and SDB are exceptionally strict. To qualify as a WOSB, the SBC must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women. The U.S. Small Business Administration (SBA) does not provide a definition for minority-owned SBCs. Instead, SBA states that a Socially and Economically Disadvantaged Small Business (previously referred to as minority-owned small businesses) must be 51% or more owned and controlled by one or more persons that meet two criteria- they are

economically disadvantaged (as determined by personal assets) and are commonly discriminated against based on one or more social factors.

Due to the complexity of the definition for SDB, and the strict criteria for both WOSB and SDB, the NCI SBIR/STTR Working Group used a softer definition of participation by one or more people from a racial or ethnic group that have been historically underrepresented in NIH-funded research. Although meaningful data on participation of minority-owned SBCs in NCI's SBIR/STTR programs is lacking, a recent publication in the FASEB Journal on diversity in the NIH applicant and awardee pools for research project grants that include SBIR/STTR (https://www.fasebj.org/doi/pdf/10.1096/fj.201800639) cited significant gender, racial, and ethnic disparities, as well as large gaps among nationally underrepresented racial minorities.

Working Group Assessment

The Working Group recognizes that the NCI SBIR program has put additional effort in recent years into meeting the goal of fostering and encouraging participation by women and underrepresented minorities.

1. Outreach: The Center began a concerted effort to include IDeA states, women-STEM organizations, and minority-STEM organizations as sites to hold off-site educational events (outreach) starting in 2015. In feedback from outreach events held in 2017, 90% of participants rated the experience as useful to very useful. However, the NCI SBIR program does not track SBIR/STTR applications resulting from these outreach events.

2. Applicant Assistance Program (AAP): The NCI was one of three NIH Institutes to pilot a program that provided proposal preparation assistance to new, previously unawarded applicants, with a specific focus on women-owned/led, minority-owned/led, and IDeA state SBCs. The program had two main goals: (1) to increase the number of underrepresented SBCs that apply for NCI SBIR funding; and (2) to increase the competitiveness of such applications. In FY 2018, 56 minority-owned SBCs applied to the AAP, compared to 36 minority-owned SBCs that applied to the NCI SBIR program in FY 2017. Interest in the program suggests that an assistance program is a good way to reach minority-owned SBCs. As the program evolves, application numbers and peer review scores should be monitored, and clear success criteria defined. Because amended applications are often required for funding, the program should be modified to go beyond just new applications and include preparation of amended applications.

3. Diversity Supplement Program for SBIR/STTR: NIH announced in 2018 an SBC-specific funding opportunity for administrative supplements to existing NIH SBIR/STTR awards to support training of racially and ethnically underrepresented personnel and thus increase diversity in the SBC workforce. A related prior funding announcement that included most NIH award mechanisms (and SBIR/STTR) had strict administrative criteria that made it difficult to use with an SBIR/STTR award. NCI received only one request in the last 6 years for this program, while it has received 4 applications in the first 6 months of the new SBC-specific program.

4. Bilingual Webinars: The NCI SBIR program has developed a series of bilingual English/Spanish webinars to be implemented in 2019. While still in the planning stages, these webinars may help improve outreach to the Spanish-speaking minority community, and this pilot may lead to related webinars focused on other minority communities.

Recommendations and Opportunities for Enhancement

1. Leverage and learn from organizations making progress on geographic diversity in various kinds of settings, such as incubators, accelerators, or Cancer Centers. Geographically diverse areas have unique needs. To support a diverse landscape of needs, this recommendation is for the NCI SBIR program to strategically listen and learn from geographically diverse areas to identify potential common areas for support.

2. Dedicate focused efforts by NCI SBIR staff to promote educational events and initiatives to SBC awardees in geographically diverse low-resource environments in the U.S. Due to low funding success rates for companies in low-resource settings, it is recommended that Program Directors work closely with promising funded companies from low-resource settings to ensure that they have access to information on initiatives, funding announcements, etc.

3. Increase representation of persons from low-resource settings on NIH/NCI peer review panels, and on any other NCI SBIR-organized initiative planning committees or workshops. Increasing geographic diversity on such panels will enable and hopefully ensure appreciation for the unique challenges faced by SBCs in low-resource settings.

4. Explore options to set up an NIH or NCI system to track participation by women and minorities in NCI SBIR-funded SBCs going forward. It is important to capture information that goes beyond majority ownership and that addresses other critically important SBC roles, as discussed above. Our research has indicated that many robust ecosystems have at least 20% of their companies founded by women, and/or have women in the Executive Suite.

5. Require representation of women and minorities on NIH/NCI SBIR/STTR peer review panels, and on other NCI SBIR-organized initiative planning committees or workshops to ensure that women and minorities have an active voice in peer review and public advisory bodies. The Working Group recognized that it may be a challenge to recruit enough women and underrepresented minorities to these roles if few of these individuals are known to NIH. Accordingly, the NCI SBIR program should encourage qualified women and underrepresented scientists to volunteer for peer review as part of normal outreach presentations given across the U.S. every year. The recommended goals for representation on the major classes of committees are as follows:

    a. NIH SBIR/STTR Peer Review Panels Organized by the NIH CSR (approximately 125 panel meetings per year). The Working Group was unable to identify a current NIH target benchmark for the inclusion of women and minority scientists on NIH peer review panels. However, recent data obtained from the NIH Office of Extramural Research indicates that in 2018 the average NIH SBIR/STTR peer

review panel was comprised of 27% women, and 9% underrepresented minorities or race withheld. Based on statistics obtained from a recent National Science Foundation (NSF) report on the gender and ethnicity breakdown of new PhDs recipients over the past 10 years, the Working Group recommends a new near-term target of 35% women on NIH SBIR/STTR peer review panels, with a longer-term goal of 40% women within 5 years. Additionally, these panels should be comprised of 10% underrepresented minorities. This applies to the NIH Omnibus SBIR and STTR FOAs (under which the majority of NCI SBIR/STTR grants are funded), and to a small number of targeted NCI SBIR/STTR Program Announcements as well.

b. NCI SBIR/STTR Peer Review Panels Organized by the NCI Division of Extramural Activities (approximately 20 panel meetings per year). The Working Group recommends the same representation targets as for NIH CSR panels above. This applies to NCI SBIR Contracts, and to RFAs, such as the NCI Phase IIB Bridge award.

c. NCI SBIR Investor Initiatives, and Other Targeted Workshops (one to two panel meetings per year). Because the NCI SBIR program has control over the organization of these panels, but it does not have access to large databases of expert personnel maintained by NIH peer review staff, and there is evidence that minorities are underrepresented in the investment world, the Working Group recommends a target representation of 20% for the combination of women and underrepresented minorities.

6. Continue to expand outreach/educational activities for women- and minority-focused organizations (e.g., Women in BIO, the National Society of Black Engineers, and other relevant organizations) to ensure they have access to NCI SBIR/STTR program information.

7. Utilize NCAB members as connectors and catalysts for existing women- and minority-focused programs across the U.S. (e.g., Springboard, The Indus Entrepreneur, Propel X, and the Goldman Sachs 10K Women Initiative).

Topic 5: NCI SBIR Resources Beyond Funding

Background

The NCI offers a range of programs and resources for SBIR/STTR grantees and applicants. Programs can be roughly categorized as those which improve the quality of the application and the entrepreneurial skills of the team, and those which improve the commercial and clinical outcomes of successful grantees. Programs 1-4 below are directed at the pre-award stage of the SBIR process, while programs 5-8 are directed towards awardees. Programs 9-10 are offered trans-NIH, served by external contractors, and are independent of NCI SBIR. The Niche Assessment Program (NAP) provides a market research report focused on the commercial opportunity of the technology being developed and can be utilized by the SBC during the Phase I project period. New legislation allows SBCs to request $50K in "technical assistance" funds to support resources equivalent to participation in the Commercialization Accelerator Program (CAP). The option to request $50K assistance funds precludes participation of that SBC in the NIH CAP program.

Current Programs and Resources

1. Outreach activities to expand and enhance applicants and awards
2. Application Assistance programs
3. Webinars to help new entrepreneurs with IP, regulation, strategy, etc.
4. I-Corps entrepreneurship training for NCI/NIH SBIR/STTR awardees
5. Networking with investors and corporate strategic partners
6. Workshops on federal resources for commercialization (TRECS) and targeted areas
7. Award oversight (staff input on technical or commercialization issues)
8. Phase IIB Bridge matching fund award program
9. NAP
10. CAP

Working Group Assessment

Activities directed at developing competitive SBIR/STTR applications can increase the diversity of the applicant pool, de-mystify the electronic application process, help entrepreneurs focus on key regulatory and commercial points, and enhance the overall quality of translational science. The keys are to keep these programs scalable for staff, to use outside contractors and resources when appropriate, and to monitor the programs using metrics. Many NCI programs work well but can be enhanced (see below). NCI-directed and targeted programs may have more impact than more general trans-NIH initiatives, and resources should be prioritized for the former.

Recommendations and Opportunities for Enhancement

1. FDA Regulatory Education:
    a. Educational webinars in collaboration with FDA, tailored to different audiences based on stage of technology development, technology type, and disease focus.
    b. Resources web page that includes collected and curated FDA guidance for technology areas that are most applicable to NCI-funded SBCs.
    c. Facilitated interactions between FDA and SBIR companies to include a workshop with 1:1 meetings, FDA small business informational day, and promotion of FDA seminars.
    d. Survey of NCI SBIR-funded companies to identify particular regulatory pain points and modify educational resources according to the feedback.
2. Peer-to-Peer Mentoring Program:
    a. With a goal to connect founders/CEOs of NCI SBIR-funded SBCs so they can share lessons learned, best practices, advise fellow founders/CEOs on startup issues, and provide an overall support network, we recommend resources be prioritized for this new program.
    b. Suggested approach would be piloting two peer-to-peer mentoring groups:
        i. In Person – a group of ~10 CEOs meets every two months in person. SBCs would be from the same geographical region.
        ii. Virtual – a group of ~10 CEOs meets every two months over videoconference. SBCs will be curated by NCI staff factoring in geographical diversity (IDeA states) and gender diversity.
    c. NCI will have training/facilitation by an expert on peer-to-peer mentoring (http://forumresourcesnetwork.com/).
3. Enhanced Capacity for I-Corps Training:
    a. We recommend incorporating NCI-designated cancer centers and academic teams as participants in the I-Corps at NIH program. Until now, I-Corps at NIH has been offered to SBIR companies. We recommend offering the program to NCI-funded academic teams. This can be an effective vehicle for preparing teams to form companies and compete for SBIR funding.
    b. Offer I-Corps in conjunction with a new Phase 0 Concept Grant program. Another Working Group Team has proposed (see Topics 2 & 3, recommendation 5) offering Concept Grants to support pre-Phase I SBIR activities (e.g., small scope experiments to collect preliminary data). We recommend requiring these Phase 0 awardees to participate in some form of I-Corps commercialization training.
    c. This expansion of I-Corps would require increasing the number of instructors who are trained to teach I-Corps at NIH in response to the increased demand.

4. Expanded Outreach to Private Sector Investors (Venture Capital, Angels, and Corporate Strategic Partners):
    a. Customize and implement Customer Relationship Management solutions to track communications with investors in a scalable manner.
    b. Develop new communication formats and strategies to engage the existing investor network in a more proactive and continuous manner.
    c. Leverage the value of investor showcase efforts by more proactive preparation of showcase companies including pitch-coaching and preparatory briefings.
    d. Conduct workshops to obtain investor perspective on potential NCI SBIR priority topic areas in which small businesses are poised to make key advances.
5. Periodically assess the usefulness and impact of all the above planned and existing resources by surveying stakeholders, including SBCs and investors, and use the information to allocate resources and/or to modify the resource program offerings.

Implementation and Guidance

Focus on Scalability: Several of the programs are scalable using web-based information and portals. Regulatory education, webinars, and application assistance are good examples of this. Other programs such as links to next stage funding may require workshops and hence NCI staff time. Having programs that educate new entrepreneurs are important, but they must be balanced with programs that support more experienced investigators. Keeping programs scalable is essential given the size of the NCI SBIR team.

Focus on Metrics and Measure Effectiveness: There are two classes of primary stakeholders: potential grantees (applicants) and successful grantees. In addition, there are a wide range of secondary stakeholders including investors, cancer patients, cancer providers, and pharma.

Project management and oversight are primary activities of NCI SBIR program staff. The relative impact of the optional programs remains to be determined, but metrics such as enhanced success of applications, leverage of private investments, and increased movement of therapies, devices, and diagnostics into clinical testing and practice, will help provide insights.

Topic 6: What Resources Should NCI SBIR Offer to Academic Innovators?

Background

Academic investigators make significant contributions to NCI-funded SBIR and STTR projects. A recent portfolio analysis of FY 2017 NCI awards revealed that $18M (17%) of SBIR and $9M (44%) of STTR grant funding was subcontracted to academic institutions. The STTR program, in particular, provides an excellent opportunity for academic institutions to collaborate with small businesses and spin-out companies, since ≥30% of the work under an STTR award must be performed at a non-profit research institution (e.g., university). While these data indicate that academic investigators routinely participate in the SBIR/STTR programs, new strategies to better assist academics may accelerate commercialization of innovations discovered in university laboratories. The NCI SBIR Development Center currently provides training opportunities and resources, including the Investor Initiatives and Innovation Corps (I-Corps) programs, to assist current SBIR/STTR awardees. Feedback on these programs has been overwhelmingly positive, and participating companies have achieved many positive outcomes and significant commercialization milestones. Experience with these initiatives suggests that mentoring assistance, development and commercialization training, and networking with business experts, can substantially affect the success of translational research projects.

Working Group Assessment

Academics at certain institutions face significant challenges in their efforts to commercialize new innovations. Challenges may include cultural barriers that stifle entrepreneurship, a lack of physical infrastructure to support translation and commercialization, and insufficient expertise in business and regulatory science. Cultural barriers often include the promotion of traditional academic priorities (e.g., research, publishing, service) over entrepreneurial efforts, inadequate IP management, as well as conflict of interest policies that discourage academics from commercializing innovations derived from their own research. A few academic centers have developed very robust programs and infrastructure to support entrepreneurship; thus, a possible role for the Center could be to identify, curate, and disseminate information on strategies to promote commercialization at academic centers. There may also be opportunities for the NCI to enhance local ecosystems through programs already established by the Center (e.g., I-Corps), which could be adapted for academic investigators. Such efforts would likely improve both the quality and quantity of SBIR/STTR applications received by the NCI, as well as promote the commercialization of technologies from academic centers located outside of established biotech hubs. Finally, it should be possible to develop new commercialization assistance programs in a strategic fashion to more fully leverage the efforts of other NCI extramural programs, including the NCI Specialized Programs of Research Excellence (SPORE) program, the Cancer Center Support Grant (CCSG) P30 program, and the Cancer Moonshot initiative.

Recommendations and Opportunities for Enhancement

1. Connect academic investigators with business mentoring and networking resources by making NCI SBIR Investor Initiatives and other SBIR training programs (e.g., I-Corps) available to them.

    a. Establish a Web portal of resources for academic investigators and investigators from NCI-designated cancer centers, SPOREs, and clinical trial networks.[1]

    b. Expand the NCI/NIH I-Corps program to include academic investigators; where possible, integrate efforts with existing NSF I-Corps sites and nodes, and develop abbreviated I-Corps courses suitable for time-constrained academic investigators. Foster and encourage greater participation among STTR awardees in the I-Corps program, as this program provides valuable training for academic entrepreneurs.

    c. Identify promising translational projects emanating from academic labs, and have winners present those projects to groups of investors at NCI SBIR events.[2]

2. Curate and disseminate a portfolio of educational resources highlighting successful strategies developed at individual cancer centers that can be used to facilitate translational research, technology transfer, and entrepreneurship.

    a. Identify business training and mentoring opportunities available to academic investigators interested in pursuing translational projects.[3]

    b. Share successful strategies for IP management, streamlining licensing agreements (e.g. the Carolina Express Exclusive License Agreement), and other aspects of private sector engagement.

    c. Describe strategies and incentives that can be established within academic institutions to promote entrepreneurship.[4]

    d. Raise the visibility of NIH programs that advance translational research projects (e.g. the Therapeutics for Rare and Neglected Diseases [TRND] program).

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[1] Consider allowing access to NCI SBIR resources only after evaluating an investigator's biosketch and a one-page description of the potential opportunity

[2] Consider matchmaking with disease philanthropy organizations that have product development/partnering programs (e.g., Leukemia and Lymphoma Society's Therapy Acceleration Program)

[3] Consider establishing a funding mechanism (e.g., training award) allowing academic researchers to do a sabbatical at an institution that can provide training in biomedical product development

[4] Consider aligning the goals of the NCI SBIR program and the Cancer Center Support Grant (CCSG) program by counting funding received through relevant SBIR/STTR grants as cancer-focused NIH funding during the review of competitive CCSG applications

3. Develop targeted NCI SBIR/STTR FOAs aimed at commercializing biomedical products that are aligned with (and/or build upon) other major NCI programs and scientific priorities.

    a. Use targeted funding opportunities (e.g., SBIR contract topics) to promote focused translational projects involving collaborations with NCI SPOREs.[5]

    b. Use targeted SBIR/STTR funding opportunities to incentivize collaborations between SBCs and academic investigators engaged in Cancer Moonshot programs.

[5] Consider including language in SPORE RFAs to encourage utilization of the SBIR/STTR program

Topic 7: Opportunities to Partner with NCI Intramural, the Frederick National Labs, and NCI-managed Initiatives

Background and Working Group Assessment

This topic focused on the integration of the SBIR program with other NCI resources- in particular the NCI intramural Center for Cancer Research (CCR), the Technology Transfer Center (TTC), Frederick National Laboratory for Cancer Research (FNLCR), and the NCI Experimental Therapeutics (NExT) program. The Center has collaborated in the past with CCR. First, SBIR worked with CCR and TTC on development of SBIR Technology Transfer contract solicitation topics in an effort to incentivize SBCs to commercialize inventions made in NCI intramural laboratories. Seven such topics were solicited from 2010-2013, and one has resulted in the commercialization of a tissue microarray device. Second, a limited number of research collaborations between NCI SBIR awardees and CCR labs have been very productive in beta testing products developed by industry. Third and finally, SBIR has received a small number of funding applications from SBCs that include CCR Principal Investigators as unpaid collaborators. SBIR and TTC are currently collaborating on an active SBIR-Technology Transfer FOA to recruit and support SBCs to commercialize NCI inventions.

FNLCR is a Federally Funded Research and Development Center sponsored by NCI via a contract to Leidos Biomedical Research, Inc. As a national resource laboratory, FNLCR offers resources to SBCs including nanoparticle characterization, GMP pharmaceutical production, reagents, and assays for research on the RAS pathway, imaging studies, mouse models, and a vast repository of research materials/reagents for cancer research. Collaborations with FNLCR take the form of a contractor Collaborative Research and Development Agreement (cCRADA) or a Research Collaboration Agreement (RCA). Over the past 5 years, there have been 3 RCAs with SBCs and 35 total cCRADAs, of which 3 were with SBCs. One of the advantages of collaboration through a cCRADA with FNLCR is that unlike CRADAs with government-operated labs, cCRADAs (with a contractor-operated lab) offer the option of an exclusive commercialization license to the SBC partner. Pre-established services are available to SBC from FNLCR via a Technical Service Agreement (TSA). These are fixed-cost, fixed-scope services with full cost recovery and no profit generated by FNLCR. In the past 5 years, there have been 5 TSAs and 11 Material Transfer Agreements executed with SBCs. In contrast to CCR, FNLCR is eligible to be a paid collaborator on any STTR grant, but this opportunity has been underutilized in the past. SBIR and FNLCR collaborated on a productive RAS pathway workshop a few years ago. Eleven SBCs participated, discussion was focused on how SBCs and FNLCR could collaborate, and several such collaborations were started. SBIR and FNLCR have also done a few local joint educational events for the SBC community.

The NExT program is open to academics and companies developing drugs or imaging agents. Its mission is to advance clinical practice and bring improved therapies to cancer patients by supporting the most promising new drug discovery and development projects. A range of drug development services are available on an application basis, with 3 deadlines per year and external peer review. SBIR companies applying for NExT have not been very competitive, but there are opportunities for improvement.

The Working Group focused on ways in which the NCI SBIR program can collaborate with all these NCI programs to expedite progress against cancer.

Recommendations and Opportunities for Enhancement

1. Establish a postdoctoral training program in entrepreneurship and tech transfer. This recommendation comes in part from a recent proposal from the TTC to start a training program for intramural postdocs working on a project for which an Employee Invention Report has been filed, wherein the trainee will spend one day per week working in the TTC, and will take formal classes locally through the Foundation for Advanced Education in the Sciences (FAES). This recommendation adds to the TTC proposal a formal detail (temporary work experience) at an SBIR company, as well as training in SBIR grantsmanship. The latter could take the form of a part-time postdoc detail in the SBIR office, and/or SBIR staff teaching SBIR grantsmanship in an FAES class. Most intramural postdocs will leave NCI after 3-5 years, and for those interested in going into industry, this two-year training curriculum will position them to license NCI IP and secure SBIR funding to support commercialization of NCI inventions. An application documenting CCR Principal Investigator buy-in will be required, along with a work plan and commercialization strategy. With current funding, CCR estimates it can maximally support one cohort per year and two trainees per cohort. This program will be piloted with intramural postdocs and then extended to postdocs supported under NCI-funded extramural grants.

2. Establish SBIR Development Center-NCI Developmental Therapeutics Program (DTP) Collaboration and an SBIR Administrative Supplement Program to increase SBIR competitiveness in the NExT program. This recommendation is for the SBIR Program office, as part of its regular discussion of new, peer-reviewed grant applications three times per year, to identify therapeutics applications that might be a good fit with the NExT mission. These applications will be brought to the attention of NCI DTP staff, and companies will be directed to the DCTD drug consultation service (https://next.cancer.gov/experimentalTherapeutics/form.htm) whereby NCI employees provide advice on the activities involved in developing cancer drug and imaging agents. Consultation between SBIR and DCTD staff will identify SBIR applicants/grantees that might benefit from SBIR administrative supplements to provide limited funding for additional work to strengthen the project data package and strengthen a future NExT application. The Working Group endorses this approach to improve the success rate of NCI SBIR/STTR awardees in the NExT program.

3. Establish a collaborative SBIR Development Center-NCI Intramural-NCI Frederick Entrepreneurial Training Program for contractors and incentivize their entrepreneurial activity. Strict conflict of interest rules effectively prohibit active federal employees from starting companies to commercialize government inventions and then representing the company before the government on IP matters without a “cooling off period.” The rules for contractors are much less strict, and we know of examples where they have formed a startup and then pursued a license from NIH to commercialize an NIH invention, sometimes aided by SBIR funding. This recommendation would be for an I-Corps-like

commercialization course (that includes SBIR grantsmanship training) that would be open to any intramural CCR and Division of Epidemiology and Genetics (DCEG) staff (including PIs), but primarily directed to intramural contractors who could leave their position, start a company, license NCI IP, and commercialize NCI inventions. For this to be successful, participation in this course (and entrepreneurial activity) by contractors should be encouraged by CCR, and ideally linked to incentives, which might include names on patents and royalties. A program like this could have a positive impact on commercialization of NCI inventions, and should benefit innovation, health outcomes, and the cancer research and public health ecosystem.

4. Launch joint SBIR Development Center-FNLCR Outreach Program to the small business community to increase utilization of NCI Frederick resources by SBIR awardees. This recommendation is to ramp up marketing of FNLCR resources to SBCs in the form of joint SBIR-FNLCR outreach/marketing events held nationwide. The NCI SBIR Development Center has collaborated with FNLCR in the past in a few local outreach events in Maryland, but would like to scale up this joint outreach effort. Our recommendation is to target at least five joint outreach events per year, both locally and nationally, and then to reassess SBC utilization of FNLCR resources and participation of FNLCR in NCI STTR applications every year for 5 years.

5. Establish a CCR Supplement Program to fund collaborations with SBIR awardees. CCR has recently formed an Office of Translational Resources (OTR) to facilitate interactions with industry. Intramural programs at other NIH Institutes such as the National Center for Advancing Translational Sciences (NCATS) currently have as many as 60 such collaborations active at one time, so there is strong precedent for this type of activity. OTR recently drafted a proposal to create a CCR supplement program to fund, on an internal application basis, meritorious collaborations between CCR labs and industry. This has been discussed by senior CCR staff, and there is interest in participating. This recommendation is to reinforce the idea behind that proposal, and to focus a significant part of the collaborative effort on NCI SBIR/STTR awardees. CCR would not provide a supplement without a contribution from the small business partner. For the collaboration scenario where technology is brought to CCR from outside, the industry partner would either be expected to bring a financial commitment to offset supply costs for collaborative work, or possibly some IP commitments from the small business to NCI, to demonstrate their vested interest in the project. It is expected that some SBIR awardees (those that have received capital from multiple sources) would be able to bring a financial commitment (e.g. $25K) that is not from an extramural NIH award (a prohibited source in this context). Those SBIR awardees not able to do so could bring IP commitments to the collaboration in lieu of or in addition to money; the CCR partner may request supplementary intramural funds for the collaboration if needed. For the alternative scenario where technology is brought from CCR to the outside (i.e. NCI tech transfer), the contribution of funding/IP from the industry partner would not be required, and the CCR partner could submit a supplement request to fund the collaboration with CCR funds. A tightly defined business plan with go/no-go decision points and close monitoring would be expected.

Topic 8: Enhancing NCI SBIR Program Metrics

Background

In 2016, a Commission on Evidence-Based Policymaking was established to develop strategy for increasing the availability and use of data to build evidence about government programs. The Commission is charged with studying how evaluation is currently being conducted and to make recommendations to strengthen the government's evidence-building efforts. More recently, the Office of Science and Technology Policy has implemented a Lab to Market initiative to increase the economic impact of federally funded research. One area of the Lab to Market effort is to outline recommendations to federal agencies for how they evaluate government programs that support research. These efforts at the highest-levels of government demonstrate the need for individual government programs to develop and maintain monitoring and evaluation systems capable of evaluating program successes and identifying areas for improvement.

As part of the SBIR/STTR Congressional mandate, the NAS completes a study and report on the SBIR or STTR programs of each agency every five years. The reports generated by the NAS are specifically intended to inform Congress on the activities of the SBIR/STTR programs at various agencies, as well as make recommendations for improvement. The most recent NAS report on the NIH SBIR/STTR programs was conducted in 2015. One recommendation in the 2015 NAS report was to enhance Monitoring, Evaluation, and Assessment of the SBIR/STTR programs at the NIH level and that the data collection address the entire range of congressionally mandated outcomes, not only commercialization. A full list of the recommendations can be accessed on the NAS website at https://www.nap.edu/catalog/21811/sbirsttr-at-the-national-institutes-of-health.

In response to an increasing demand for agency SBIR/STTR programs to evaluate their program, several agencies have implemented early program monitoring and evaluation activities, including NCI. The NCI SBIR Monitoring and Evaluation efforts to date have focused on two areas, outcomes and impacts. The outcomes and impacts evaluations by the NCI SBIR Development Center have been retrospective. Retrospective analyses are useful and important, but because the timeline for commercialization success of biomedical technologies is long, robust monitoring and evaluation programs should include methods for prospective analysis as well.

Working Group Assessment

- Impact analysis: The Center was the first at NIH to commission a large Impact Study on the SBIR/STTR program. This review includes an analysis of economic impact, as well as some indicators of patient/societal impact by NCI SBIR funded technologies.
- Utilization of third-party business intelligence tools: The Center developed a system to track outcomes using business intelligence tools and databases. Utilization of these tools allows the Center to follow funded technologies after the end of the award.
- Collection of ad hoc success stories: The Center has put significant effort in recent years into identifying and contacting awardees with commercial success. Demonstrating program successes is an important metric for demonstrating the impact of the program.

Archetypes

The Working Group defined an initial set of archetypes of businesses that enter the program. Defining archetypes and using their milestones is one process by which the Center can begin to define their ideal customer and develop leading versus trailing metrics for the program.

- ***An Academic Spinout.*** Dr. Avrum Spira began development on a diagnostic test for lung cancer with R21 and R01 funding. He founded Allegro Diagnostics and received SBIR funding to move his discovery-based research into product development. SBIR funding was used for early proof of concept of the test, later commercialized as Percepta. Percepta was acquired by Veracyte following SBIR funding and several fundraising rounds. Veracyte conducted registry trials with 500-600 patients in approximately 50 medical centers, and the results from the trials were later used to gain approval for Medicare coverage in 2017. Percepta is currently on the market and uses advanced genomic technology to improve lung cancer diagnosis for patients.

- ***A Non-Academic Startup.*** After a personal experience with cancer therapy, an entrepreneur identified a problem facing oncology nurses: recurrent exposure of low-dose chemotherapeutics during drug preparation and administration causes serious health issues in the oncology nursing staff. This entrepreneur partnered with an engineer to found Corvida Medical, and develop a closed system where chemotherapeutics could be reconstituted and loaded into delivery devices in a closed system, limiting repeated exposure to nurses. A study of the Halo Closed System Transferring Device at 13 Cancer Centers across the U.S. in 2017 demonstrated lower surface contamination when the system was used.

- ***An Established Small Business.*** Celdara Medical in-licenses therapeutic candidates from academic institutions, along with agreements for inventors to dedicate protected time to the development of a product. The company advances products to a point that makes them attractive to larger entities for commercialization. An early project for Celdara was the development of an allo-CAR-T cell. The product was advanced with SBIR funding, and subsequently sold to Celylad. Celeyad recently announced the acceptance of their IND by FDA for this product named CYAD-101, the first non-gene edited allo-CAR-T candidate.

Recommendations and Opportunities for Enhancement

1. Every five years, commission a study to evaluate the outcomes of the NCI SBIR/STTR program. There are two critical components that should be studied: the economic impact and the effect of NCI SBIR/STTR-funded technologies on health outcomes. Impact studies should be conducted by a third party, and a report should be generated based on the findings. There are several methods currently in use or under development for economic impact studies. Therefore, this recommendation does not specify an analysis method, but supports flexibility in the method used to evaluate the program between quinquennial evaluations.

2. Implement an intake survey for new awardees. An intake survey would allow NCI to establish a baseline from which meaningful progress during and after the SBIR/STTR project can be evaluated. Critical metrics for this survey should include participation in the small business by women and minorities, private funding, number of employees, development stage, and regulatory filings.

3. Implement better utilization of current reporting. Currently the structured Phase II final report for NIH SBIR/STTR projects is used about 40% of the time. The NCI SBIR/STTR programs should set a goal of 90% compliance for this report. One challenge to a 90% benchmark of success is that the structured Phase II final report is not a mandatory format and the NCI has limited ability to impose consequences for non-compliance. Therefore, the NCI should explore financial incentives to improve compliance, e.g. final payments contingent upon final reporting for grant awards.

4. Develop and implement a set of leading metrics for applicants and funded small businesses. Some other agencies, e.g. NSF, have developed a set of leading metrics to help identify companies that are well positioned to take advantage of the program. Examples of leading metrics used by NSF that NCI should evaluate in their own program include age of company, private financing prior to SBIR application, and previous federal funding.

5. Create and maintain a database of success stories and "archetype" companies. Development of a series of archetypes can help the Center to outline their ideal customer and identify their most impactful metrics by evaluating milestones and achievements made by these archetypes. The overall goal of maintaining archetype companies is to develop a long-lasting dialogue, learn from their development path, and use the lessons learned to refine the metrics by which the program is measured.