MINI-REVIEW

Investor initiatives program: Public-private partnerships to expedite commercialization for NCI-funded small business entrepreneurs

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Abstract
The National Cancer Institute’s Small Business Innovation Research Development Center (NCI SBIR) provides federal research and development funding and commercialization resources to more than 400 small businesses each year developing novel technologies to prevent, diagnose, and treat cancer. Although federal funding is vital for life science startups at the early stage of development, it is often insufficient to translate the technology from discovery to commercial product. Early-stage startups must connect to follow-on capital and resources to bring NCI-funded technologies to patients. Most startups face challenges in securing additional funding due to lack of access to investors and strategic partners and the ability to effectively pitch their technology. In 2015, the NCI SBIR started the Investor Initiatives program to connect funded small businesses with targeted investors and strategic partners to address the aforementioned obstacles. This program leverages an extensive network of investors and partners to conduct business-focused reviews and provide pitch coaching. The program incentivizes earlier collaborations between NCI-funded companies and private investors through various channels. The program has supported 117 companies from years 2016–2019 to attend 27 investor showcase events. Follow-up surveys show that the program and the assistance offered by NCI SBIR have contributed to a total of 32 completed deals as of April 29, 2020. This paper will discuss the Investor Initiatives program and its outcomes from 2016 to 2019 and demonstrate the effectiveness of a federal program that leverages public-private partnerships to assist portfolio companies with raising follow-on funding to accelerate the translation of research into clinical practice.
INTRODUCTION

A critical goal of the Small Business Innovation Research Program (SBIR) and the Small Business Technology Transfer (STTR) Programs is to increase private-sector commercialization of innovations derived from federal research and development (R&D) funding. With an annual budget of more than a billion dollars, the SBIR and STTR programs at the National Institutes of Health (NIH) are one of the largest sources of seed capital available to commercialize life science innovations for small businesses owned and operated in the United States. The SBIR/STTR program is structured as a three-phase program: phase I focuses on early feasibility or proof of concept, phase II supports R&D toward a product, and phase III aims to pursue commercialization resulting from phase I/II R&D activities. Although the NIH provides funding support via federal grants and contracts for phase I and phase II SBIR/STTR, phase III is expected to be accomplished without federal funding. However, phase I/II funding alone is generally insufficient to bring a life science technology from discovery to a commercial product as R&D costs can exceed $2 billion, especially for drug development projects. Securing external capital is a crucial step in the commercialization pathway.

With a budget of ~ $180 M in 2020, the National Cancer Institute (NCI) has the largest SBIR/STTR program within the NIH. The program has a unique management structure and has been managed centrally through the SBIR Development Center since 2008. This centralized management focuses on supporting companies that are product-focused and committed to getting technologies into the clinic by providing not only nondilutive capital but also a variety of critical commercialization resources, like entrepreneurship training and access to expertise. One such resource essential for the commercialization of NCI SBIR-funded technologies is the Investor Initiatives program developed to effectively connect portfolio companies with third-party investors and strategic partners (Figure 1).

PROGRAM EVOLUTION

From 2009 to 2014, the NCI SBIR organized four Investor Forums in Boston and California to showcase promising NCI startups to investors and strategic partners. Each of these forums featured ~ 20 NCI SBIR-funded companies that were invited to pitch to a select group of investors, strategic partners from large Pharma and MedTech companies, and philanthropic organizations. The NCI SBIR Investor Initiatives team was instrumental in ensuring that these events addressed the goal of showcasing NCI-funded companies to a large group of follow-on funding sources. The participating portfolio companies leveraged connections made at these four Investor Forums resulting in at least 10 completed deals.

Although this model was successful in establishing partnerships, there were several drawbacks to this approach of connecting portfolio companies to investors. The NCI SBIR supports a diverse portfolio of 400–450 active projects at any given time. These projects span technology development stages, and include various technology areas, such as drugs, diagnostics, devices, software, and research tools and are located across the United States. It was challenging to host a single event to showcase the diversity of technology types at various development stages to appropriate investors and partners. Constrained federal resources also meant that the event could only be scheduled every other year, which precluded more frequent interactions between investors and portfolio companies. Thus, in 2015, the NCI SBIR Program implemented a holistic approach with a set of core elements to develop a more timely, scalable, and efficient Investor Initiatives program to address these drawbacks.

The goal of the modified program was to provide NCI SBIR portfolio companies with better access to investors and strategic partners and to work closely with the private sector partners to identify emerging and under-funded areas where federal funding can accelerate development. There are four essential elements to this modified program:

1. Building and expanding an active investor network
2. Investor review of the technologies and timely feedback to portfolio companies
3. Coaching and funding support to portfolio companies to attend investor showcases
4. Identifying scientific and market trends to promote emerging and under-funded areas

Below, we discuss each of these elements and share outcomes from 3 years of the modified Investor Initiatives Program.

FEATURES OF THE MODIFIED INVESTOR INITIATIVES PROGRAM

Building and expanding an active investor network

The NCI SBIR has spent more than 10 years growing and maintaining a network of investors and strategic partners who are interested in working with the Program. The NCI SBIR staff make a concerted effort to widen the investor network by attending conferences and investor
showcases, such as the JP Morgan Healthcare Summit, BIO International Convention, BIO Investor Forum, RESI Conference, the Precision Medicine World Conference, BioNetwork Partnering Summit, Life Sciences Summit, and MedTech Strategist Innovation Summit. The team maintains an active list of investors and uses a customer relationship management tool to keep track of their specific investment focus, deal size, and ideal technology stage for investment, and other factors. The network has now grown to more than 350 active investors and strategic partners. To keep the investor network abreast of the program and portfolio companies’ activities, the NCI SBIR publishes a quarterly newsletter addressed to investors to share information about companies with innovative products, recent deals, and new funding opportunity announcements. The NCI SBIR also regularly shares executive summaries of promising companies both via newsletter and email updates. Investors collaborate with the SBIR program primarily in four different ways: (1) participating in the annual SBIR investor review process, (2) connecting startups they interact with or their own portfolio companies to the SBIR program, (3) helping the SBIR team identify market trends and emerging technology areas, and (4) sharing areas they are interested in to receive an updated, NCI-curated portfolio list.

**FIGURE 1** The NCI SBIR Investor Initiatives team aims to introduce portfolio companies to investor/partner contacts in various ways on an ongoing basis. These activities include the annual review process where selected companies are given NCI support to pitch at a conference, pitch coaching support, sharing of the active portfolio document to interested investors/partners, partner-led activities that involve NCI SBIR portfolio companies, and working with investors/partners to identify emerging areas and trends. NCI SBIR, National Cancer Institute’s Small Business Innovation Research Development Center
Investor review and feedback

The NCI SBIR program supports 400–450 portfolio projects at any given time. Every year, to determine the most exciting portfolio companies to showcase to investors and strategic partners, the program solicits written pitch-like applications3 from the portfolio companies that include details such as current progress, stage of development, fundraising plans, and milestones. To ensure that R&D activities are still relevant, applicants are restricted to those who have received a phase I NCI SBIR/STTR award in the past 2 years or who have received a phase II NCI SBIR/STTR award in the past 4 years.

The Investor Initiatives team then recruits a team of 60–80 active investors, corporate business development representatives, and commercialization experts from the NCI’s network to review these applications. It is important to note that this review is separate from the technical review performed in the NIH’s peer-review process. Each application is assigned to three to five reviewers to get a variety of expertise and to maximize the visibility of the company to investors. While assigning reviewers, the team ensures that the company matches the reviewers’ investment interests and that the company was not assigned to them in any previous reviews or to any of their colleagues in the current review. The reviewers assess each application for several criteria, including technology innovation, potential patient impact, scientific progress, stage of development, market opportunity, unmet clinical need, competitive advantage, management team, intellectual property (IP) strategy, and the likelihood of attracting requisite financial investment. In addition to the written evaluations, reviewers attend a conference call to discuss select applications in further detail.

The Investor Initiatives team considers the written evaluations and feedback from the reviewer calls to select 30–40 portfolio companies to showcase for the year. Each selected company is matched to one investor showcase event that aligns with the company’s technology focus area, stage of development, and investment needs. The value of the review process is not just in the selection of the best companies to showcase. Each applicant, irrespective of their selection status, receives anonymized written review feedback outlining the reviewers’ critiques and suggestions to improve their appeal to investors and strategic partners.

Coaching and funding support

To prepare the selected companies for the matched investor showcase event, the NCI SBIR offers complimentary pitch coaching consults to interested companies to provide feedback on their pitch presentations from program staff and/or external experts, including investors and strategic partners. The NCI SBIR also offers financial assistance by paying the registration and presentation/partnering fees for up to two company representatives at the matched showcase events. In the past 4 years, selected companies have been sent to well-established investor showcase events organized by relevant industry specific organizations.

In collaboration with the showcase organizers, the Investor Initiatives team educates the participating companies on the best practices and strategies to optimize their showcase experience. This includes actively leveraging the partnering systems and other networking opportunities.

Connecting companies to investors with investor book and searchable portfolio list

Beyond the investor showcase events, the Investor Initiatives team showcases the selected portfolio companies to both the existing investor network and new contacts by creating and sharing an Investor Book each year containing a short executive summary of all the selected companies.

The Investor Initiatives team also maintains and shares a regularly updated and easily searchable list of funded portfolio companies categorized by technology type, stage of development, cancer indication, gene target, and several other relevant fields. Based on investor interest from either the Investor Book or the portfolio list, the NCI SBIR regularly facilitates introductions between companies and investors.

Identifying scientific and market trends

In addition to connecting companies with investors and partners, the team also engages with the investor network on an ongoing basis to receive inputs on market trends and emerging technology areas. Early federal investments in emerging technology sectors can often prime the field for future private sector investments. These conversations keep the NCI SBIR program abreast of the activities across the life sciences private sector.

PROGRAM OUTCOMES

Each year, around 100 eligible companies apply to the Investor Initiatives program, and around 30–40 companies are selected to participate. A total of 117 companies...
were selected for the three rounds of the program from 2016 to 2019 and were matched to a total of 27 showcase events (9 unique events in total). These showcase events include Angel Capital Association Annual Meeting, BIO International Convention, BIO Investor Forum, BioNetwork Partnering Summit, Redefining Early Stage Investments (RESI) Conference, Medical Alley Innovation Summit, The MedTech Conference organized by AdvaMed, Life Sciences Summit, and the Precision Medicine World Conference.

A little more than half (56%) of the selected companies were focused on therapeutics, 18% on devices, 19% on diagnostics or research tools, and 7% on digital health or behavioral modification technologies (Table 1).

Feedback from the companies attending pitch events is collected shortly after the event (short-term feedback) and 12–18 months after the event (long-term feedback). During the 2016–2019 period, short-term feedback was obtained from 101 of 117 companies, a response rate of 86%. The selected companies from this period held more than 1085 one-on-one meetings with potential investors and partners during their matched conferences (Table 2). More than 800 of these meetings included investors with moderate or high interest in the portfolio companies as perceived by the respondents. Around 80% (81/101) of the respondents thought that the event was extremely or moderately useful in connecting with potential partners/investors. An average of 69% (70/101) surveyed thought that they moderately or greatly benefited in gaining exposure or visibility. Additionally, 94% (60/64) of companies who reported that they received mentoring from either NCI SBIR staff or external industry mentors leading up to the event noted that it was mostly or extremely useful. Importantly, 90% (91/101) of the companies reported that they would not have been able to attend their matched event without NCI support, amplifying the need for this initiative.

The response rate for the long-term feedback was 83% (97/117). From 2016 to 2019, a total of 79 completed deals were reported by 44 companies. Twenty companies reported that NCI SBIR support was integral for 32 deals. Additionally, 19 deals from 12 companies were a result of the company meeting or reconnecting with an investor at the NCI-paid event, a direct introduction to the investor by the NCI team, or the investor was a reviewer for the company’s NCI grant application. NCI involvement was also credited in helping 34 deals that were still in negotiation, with 20 of those directly attributed to the NCI Investor Initiatives efforts (Figure 2). Companies that report deals in the feedback surveys are not required to disclose the deal size or investor name and the NCI SBIR team follows up accordingly to gather any available information.

In addition, sharing the portfolio document and Investor Book with the investor network has led to more
than 60 direct introductions between investors and portfolio companies since December 2018. The NCI SBIR program is actively tracking these interactions and anticipates that a number of additional deals will result in the future.

Examples of successful deals from companies participating in Investor Initiatives include:

- CellSight Technologies secured an investment and collaboration with Boehringer Ingelheim to fund a clinical trial of CellSight’s SBIR-funded technology. CellSight initially connected with Boehringer Ingelheim at an NCI-paid event.

- JBS Science met with Richen-Forge Holding at two industry showcases through participation in Investor Initiatives, culminating in an agreement for a collaboration and validation study funded by external investment.

- On Target Laboratories secured $40 M in funding from Johnson & Johnson Innovation – JJDC. The companies were introduced at a Johnson & Johnson-organized showcase of select SBIR Investor Initiatives companies.

- Etubics Corporation received a $17 M investment from NantCell. Etubics’ application to the Investor Initiatives program was reviewed by the investor involved in the deal. Etubics later merged with NantCell. The merger resulted in funding for continued clinical development of Etubics’ NCI-funded therapeutic vaccine platform.

- KIYATEC has secured an investment from Esperante Ventures. KIYATEC initially connected with Esperante at the BIO Investor Forum through the Investor Initiatives program.

**DISCUSSION AND NEXT STEPS**

The NCI’s success rate in catalyzing investments and partnerships for NCI SBIR awardees is the strength of the

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**TABLE 2** Short-term feedback responses show how many one-on-one meetings respondents were able to hold as a result of their participation in Investor Initiatives

| Year     | Survey respondents | Total meetings | Average meetings |
|----------|--------------------|----------------|------------------|
| 2016–2017 | 34                 | 281            | 8.26             |
| 2017–2018 | 30                 | 330            | 11               |
| 2018–2019 | 37                 | 476            | 12.86            |
| TOTAL    | 101                | 1087           | 10.71            |

**FIGURE 2** Results of the long-term feedback survey showing NCI involvement in reported deals by selected Investor Initiatives companies. NCI, National Cancer Institute
program. Some selected companies were successful in raising funds without direct contribution of the Investor Initiatives program. This is testament to the excellence of the NCI-funded companies in general and the Investor Initiatives selection process in particular. Based on the short-term data, gaining visibility and pitch improvement are other secondary benefits of this program. A high percentage of companies reported that they would not be attending these meetings without NCI support, reflecting the importance of NCI’s program. On a broader scale, this speaks to the early-stage nature of NCI-funded companies, where many companies are still managed by academic founders for whom connecting with investors is a novel concept.

To successfully raise investments and/or develop partnerships, ideally the company must have a technology based on strong scientific rationale and backed by robust data, a sound business development plan, an experienced management team, and a robust patent portfolio. As is the norm for pitch competitions, companies that can competently articulate their value proposition and delineate their development pathway fare better in the investor review regardless of the technology type and development stage. Even companies that are in early preclinical development and not quite ready for immediate investment benefit from the process by gaining visibility with the investors and receiving their feedback early in the process. To increase participation from new awardees, the NCI SBIR has posted information about the investor initiatives review program along with the application on the NCI SBIR website (www.sbir.cancer.gov). This website also lists the investor books with executive summaries of previously selected companies as a guide to future applicants as well as for potential new investors.

Although the deals catalyzed by the NCI SBIR Investor Initiatives program are promising, the team continues to improve the program by constantly analyzing feedback and restructuring the application/review process or conference matching process as needed. For example, one modification for the 2020 cohort was the incorporation of video pitches and video pitch coaching as a reflection of the increasingly virtual nature of pitching. In addition, given the impact of coronavirus disease 2019 (COVID-19) on industry conferences in 2020, the team also planned and hosted a September 2020 Virtual MedTech Showcase, one of the first virtual events in the MedTech space, with a selection of Investor Initiatives companies as well as companies from the broader portfolio. The Investor Initiatives team continues to track the deals that are under negotiation as well as the interactions that are taking place as a result of NCI introductions. Some companies stumble in preparing an effective pitch that is tailored toward the investor audience. In addition, because of the constantly evolving early-stage funding landscape, small businesses do not always know which type of funding vehicle/strategy would be optimal for their technology. To address this, the NCI SBIR is instituting an industry mentoring program with experienced entrepreneurs to guide companies on business and investment strategies.

Another goal set by the team is to improve Diversity, Equity, and Inclusion (DE&I) in the SBIR program and the Investor Initiatives program. Based on the feedback surveys, 13 of the selected companies were majority women-owned, 32 were partially women-owned, 22 were founded or co-founded by women, and 28 companies had women in a C-level role. One company reported being majority minority-owned, 11 companies were partially minority-owned, seven were founded or co-founded by a minority, and 11 companies had minorities in C-level roles. Thirty-two percent (14/44) of the reported completed deals were from companies with under-represented researchers in C-level leadership positions. There is a concerted effort by the NCI SBIR team to perform targeted outreach and create focused mentoring programs for NCI-funded startups to improve DE&I in the companies selected for the Investor Initiatives program.

The Investor Initiatives program at NCI SBIR is supported by administrative funds to improve commercialization opportunities of awardees. The SBIR/STTR Reauthorization Act of 2011 authorized a pilot program permitting Participating Agencies to request up to 3% of their SBIR funding to support assistance for administrative, oversight, and contract Processing Costs. Each year, around $75,000 is allocated to pay for company registrations and partnering fees at events, leading the program to have a very robust return on investment, as proven by outcomes described previously.

The NCI SBIR team is also developing other opportunities to increase industry exposure for startups. One successful program was the SBIR Phase IIIB Bridge Award that provided up to $4 M in nondilutive grant funding to companies that have completed SBIR phase II awards and need funds for further validation and development to cross the “Valley of Death.” Phase IIIB applicants are encouraged to secure a 1:1 match from outside third-party investors to qualify for the program. The phase IIIB program has been successful in incentivizing third-party investors at an early stage due to the promise of nondilutive funding from the NCI and the rigor of technical validation for SBIR-funded companies through the NIH peer review process.

In addition, the Investor Initiatives team is planning a scalable industry mentoring program that would connect NCI SBIR-funded small businesses with mentors (investors, industry experts, and SBIR alumnai). Many startups are owned and operated by academic investigators, and
CONCLUSIONS

The NCI SBIR Investor Initiatives Program supports startups in the areas of pitch development and networking with potential investors/partners at NCI-paid events. This federal program goes beyond merely funding promising small businesses with SBIR and STTR grants and contracts and further assists these companies in taking necessary steps that will help accelerate their technology along the path of commercialization. NCI support and mentorship prior to matched conferences are increasingly seen as extremely useful by the small businesses that participate.

There is increasing interest in the program from the industry and investor community, as demonstrated by the steady and growing investor/partner involvement in the review process over the years. Growing the NCI SBIR investor network and tracking outcomes of the program based on the short-term and long-term feedback surveys is critical to maintaining and growing the program even more.

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CONFLICT OF INTEREST

The authors declared no competing interests for this work.

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