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SBIR/STTR Grants: Introduction and Overview

Summary

- The purpose of the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) grant mechanism is to stimulate technological innovation through facilitating private-sector commercialization of research advances.
- Small business entities do not need to relinquish equity in exchange for SBIR/STTR funding.
- A key difference between SBIR and STTR grants is that the STTR requires university participation, which is optional for the SBIR.
- SBIR/STTR applications can be submitted in conjunction with more traditional R01/R21 grant applications and are ideal for exploring the commercialization potential of research results.

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SBIR/STTR Grants: Introduction and Overview

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Topic Relevance by Timeline

Summary

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Introduction

In 1983, Genzyme was a small company founded by a research technician working at Tufts University and a serial entrepreneur without prior experience in the biotechnology world. The company received its first \$62,000 SBIR grant from the Department of Health and Human Services to develop methods for large-scale enzyme purification shortly after its founding. Over the course of thirty years, Genzyme would become the third-largest biotechnology company in the world, receiving a total of seven SBIR awards within its first decade. In 2011 the company was acquired by pharmaceutical giant Sanofi for \$20.1 billion.

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The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are government-sponsored grant awards that are intended to promote the development of new technologies across a number of sectors. This chapter will focus on SBIR and STTR grants of the National Institutes of Health (NIH). NIH SBIR and STTR grants have some parallels to traditional NIH R01/R21 grants, however, SBIR and STTR grants are focused specifically on the development of commercializable technologies. SBIR/STTR applications have a higher chance of success in general, compared to more traditional NIH grant mechanisms. SBIR/STTR grants are excellent seed funding sources because they do not dilute the shares of the startup company, they reflect excitement about the proposed technology, encourage future diluting investment, and do not require as much scientific burden-of-proof as traditional NIH grants. The main downside to SBIR and STTR grants is that they are highly competitive and it often takes over one year to receive final decisions, which may be unacceptable to a budding company early in its life cycle.

This chapter will provide an overview of the SBIR/STTR program, while specific application details are provided in the chapter (“SBIR/STTR grants: Application Guidance”), and additional information regarding Department of Defence SBIR/STTR grants is given in the chapter “Department of Defense: SBIR/STTR Grants and Other Contracts.”

The Valley of Death

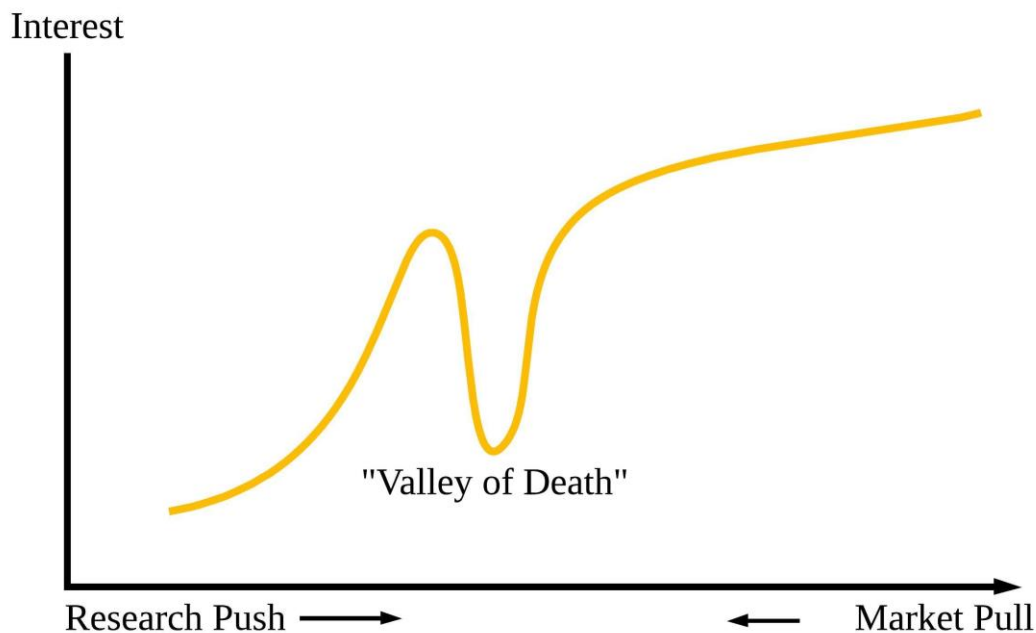
Innovative companies rely on commercializing new ideas to advance technology; however, obtaining funding to drive the development of truly innovative ideas is often difficult due to the risk-averse nature of many investors. Most investors focus on late-stage funding opportunities to minimize their exposure to the uncertainties of early-stage technology development (see the chapter “Conducting Insightful Market Research”). Consequently, many promising and innovative technologies under development often fall victim to the “valley of death,” where advances in research have pushed new technologies into the realm of possibility, but the market pull is not yet large enough to sustain further interest (Figure 1). This critical point is where federally funded programs are needed to provide further support for developing technologies.

The SBIR and STTR programs have as one of their goals that of providing seed funding for small companies to commercialize and develop innovative, state-of-the-art technologies based on the results of federally funded research. Indeed, in recent years the share of U.S. seed capital coming from the SBIR and STTR programs has increased; estimates place SBIR/STTR contributions to total U.S. seed funding within the range of 60%–65% (Ceulemans and Kolls). This growth has continued to underscore the pivotal importance of these programs in supporting small business innovation. In total, 11 federal agencies are mandated by Congress to set aside 2.5% of their annual external research budget to fund the SBIR program, and 0.3% of extramural funding for the STTR

program. These agencies include: the Department of Agriculture, the Department of Commerce, the Department of Defense (covered in a separate chapter), the Department of Education, the Department of Energy, the Department of Health and Human Services, the Department of Homeland Security, the Department of Transportation, the Environmental Protection Agency, the National Aeronautics and Space Administration, and the National Science Foundation. The broad motivations of both the SBIR and STTR programs are to:

- Stimulate technological innovation;
- Meet federal research and development needs;
- Increase private-sector commercialization of innovations developed through federal R&D funding;
- Foster and encourage participation in innovation and entrepreneurship by socially and economically disadvantaged persons and women-owned small businesses;
- Require evaluation of commercial potential in Phase I and Phase II applications;
- Serve as seed capital for early stage R&D with commercial potential. The awards are comparable in size to angel investments in the private sector and indicate the acceptance of greater risk in support of agency missions (“Tutorial 1: What Is the Purpose of the SBIR and STTR Programs?”).

Figure 1. Valley of Death.



Source: Adapted from Ford et. al.

Differences Between SBIR and STTR grants

Though related in their goal to commercialize technology developed through federally funded research by fostering partnerships between academia and industry, basic differences distinguish the SBIR and STTR programs. The main difference between them is the relationship of the researchers to the parent university during the award timeframe. In the SBIR program, the principal investigator must be employed by the small business at the time of the award (defined as at least 51% of their time devoted to the small business; they do not need to devote all of this effort to the funded application, however. For example, they could be 55% employed by the small business and devote 20% effort to a specific SBIR project). The small business can also employ a research partner through a subcontract, such as a contractor or a university, for up to 33% effort in Phase I and up to 50% effort in Phase II trials (see description of funding phases below) (“Course 6: Preparing Proposal”). In contrast, the STTR grant allows the principal investigator to be employed primarily by the parent academic institution or by the small business but requires the inclusion of a small business that must put in at least 40% effort, while the academic institution is responsible for at least 30% effort; interestingly, even though the principal investigator is at the academic institution, the STTR grant is still technically awarded to the small business partner, and the academic institution receives a subcontract from the small business partner. There must also be proof of licensure of intellectual property from the academic institution to the small business. In essence, the STTR is slightly more academically oriented than the SBIR because stronger ties are allowed/mandated by the STTR.

The success rate of NIH SBIR and STTR applications has been similar in recent years. In 2017, for Phase I applications, the success rate was 15.6% and 16.1% for SBIR and STTR grants, respectively. For Phase II, the success rate was slightly higher for STTR grants: 33.2% for SBIR and 38.6% for STTR. However, the total number of awarded STTR grants (203 awards) was much lower than the number of SBIR grants (879 awards). These statistics may influence the choice of which award to apply for. The primary differences are summarized in Table 1.

Eligibility Criteria

Both the small business applying for the SBIR/STTR funding and the principal investigator (PI) identified in the application must fulfill certain criteria to receive funding from the SBIR/STTR program. Each agency-released parent funding opportunity announcement outlines specific eligibility criteria that must be met by the date of grant, for both Phase I and Phase II funding agreements. Broadly, restrictions on applicants fall into three categories: (1) the type of firm applying for funding, (2) ownership requirements, and (3) the size of the firm.

Table 1. Comparison of SBIR/STTR.

| | SBIR | STTR |
|--|---|--|
| Academic (non-profit) research partner | Not required | Required |
| Principal Investigator | Must be >50% employed by the company <u>at the time the grant funding is released</u> (not when the application is submitted) | Must devote >10% effort; can be employed either by the company or the academic partner |
| Subcontracting | May outsource: <33% (Phase I) <50% (Phase II) | Requires that >40% of the funds be allocated to the small business and >30% of the funds to the academic partner |
| Licensure of Intellectual Property from University | Optional | Mandatory |
| Funding Success Rate (Phase I, Phase II) | 15.6%, 33.2% | 16.1%, 38.6% |
| Total Number of Applications (Phase I and II) | 4,483 | 1,137 |
| Total Number of Awards (Phase I and II) | 879 | 203 |

Adapted from <https://sbir.nih.gov/statistics/award-data> (2017 data)

The small business entity must be qualified as a “small business” by the time funding is awarded, and at least 51% of the company must be owned by U.S. citizens. An important distinction to note is that small business entities need not meet SBIR/STTR qualifications during the application process, as long as requirements are met at the time funding is received. Indeed, a 2008 report released by the National Research Council found that approximately one-fifth of firms receiving National Science Foundation (NSF) SBIR funding were business entities on paper only, beginning official business-related activities only after receiving a successful application (National Research Council). To receive SBIR/STTR funding, the business must be for-profit, have no more than 500 employees, and be located in the United States. In recent years (due to statutory changes), the NIH allows SBIR grant recipients to be 50% owned by hedge funds, multiple venture capital operating companies, private equity firms, or any combination of these (Cornell Law School). This is not the case for small businesses participating in STTR grants. If the concern is a joint venture, then each interest must mutually meet all eligibility requirements.

Finally, applicants must be registered on the SBIR/STTR company registry prior to the submission of the application. The online form for this can be found on the SBIR website at <https://www.sbir.gov/registration>. The detailed list of required registrations is covered in the chapter “SBIR/STTR Grants: Application Guidance.” Additionally, the U.S. Small Business Administrations’ “Guide to SBIR/STTR Program Eligibility” is accessible online from the SBIR website and provides a good starting point for applicants to research eligibility requirements: <https://sbir.nih.gov/about/eligibility-criteria> (“Small Business Eligibility Criteria | NIH SBIR/STTR”).

Successful applications must meet the scope and goals of the SBIR/STTR program. A proposal should be technically innovative and have the potential for meaningful commercial or societal advancement. Technical risk/innovation ordinarily means that a project has not been previously accomplished. The necessity for the award to overcome some prototype or development impediment or roadblock should be demonstrated. In general, technologies poised to disrupt a particular market will be favored. Importantly, a small business need not demonstrate prior data to apply for a Phase I award but must do so for a Phase II award.

The federal government has a broad definition of who may and may not be eligible to be a PI. Generally, PIs can be any individuals with the skills, knowledge, and resources necessary to carry out the proposed research. Under this definition, an advanced doctoral or medical degree is not a prerequisite for being named as a PI on an application. Specific requirements for the PI vary depending on the type of grant (SBIR vs. STTR) and the specific agency offering the grant. For the purposes of the SBIR, all agencies agree the PI cannot be employed full-time elsewhere during the grant period. A key distinguishing feature between the SBIR and STTR programs is that under the STTR program the PI is allowed to be primarily employed by *either* the small business applicant or a collaborating nonprofit research institution during the grant period. This can be especially attractive for an academic entrepreneur who does not wish to leave their primary job at their research institution but remains interested in partnering directly with a small business entity to explore the commercialization potential of their research work. Alternatively, the company can submit an SBIR application with a subcontract to an academic partner, in which case an employee of the company is the PI of the grant application and the academic faculty member can be the PI of the subcontract. It is recommended that the investigator document a formal relationship with an expert investigator in the field to demonstrate sufficient mentorship. A prior history of successful collaboration between the academic investigator and the small business team is also helpful, but not required. Additionally, consistent with the broad goal of the SBIR/STTR program, further emphasis is placed on awarding applicants with principal investigators from underrepresented racial and ethnic groups or disabled persons.

Funding Phases Overview

Both the SBIR and the STTR grants have three primary phases of funding, representing progressive stages of technology development. Each funding phase has distinctly defined goals and offers differing amounts of funding toward achieving those goals. The three primary phases are organized as follows:

Phase I: The two broad goals of Phase I are (1) to establish the technical merit and commercial potential for a project, and (2) to demonstrate the quality of performance of the small business entity prior to awarding further funding. Aims for a Phase I SBIR/STTR application generally involve performing market research, prototype development, and proposing a small open-label pilot trial consisting of 10–20 subjects. The maximum available funding for NIH Phase I awards is \$225,000 over 6 months for an SBIR grant or over 12 months for an STTR grant; consequently, applicants are encouraged to ensure budgets and timelines in their proposal are consistent with the scientific scope of the proposed research. The application generally consists of a six-page research plan, along with other NIH-required documents.

Phase II: The broad goal of a Phase II grant is to continue research and development efforts associated with the Phase I grant. Phase II grants are contingent on a successful Phase I grant, the scientific and technical merits of the project, and its commercial potential. Small businesses must have been awarded a Phase I grant to be eligible for receiving a Phase II grant. Aims for a Phase II SBIR/STTR application typically involve additional technology development, and applications for an SBIR/STTR grant that allows clinical trials may include a larger, randomized trial composed of >50 subjects. Both the SBIR and STTR programs will generally offer \$1 million over two years. Phase II applications will generally require a 12-page research plan, in addition to a 12-page commercialization plan and other standard NIH-required documents.

Phase III: The broad goal of Phase III is for the small business to pursue commercialization objectives resulting from Phase I/II activities with non-SBIR/STTR funds, thus there generally is no funding from the government for this phase. Some federal agencies may offer follow-on, non-SBIR funded research, development opportunities, or production contracts for products, services, or processes that are intended for use by the U.S. government.

In addition to the above phases, some federal agencies offer a combined Phase I+II “fast-track” program or a Phase IIB program, which is a competitive extension of a Phase II or fast-track project beyond the final year. Progress made in the project over the last funding period is required for Phase IIB funding consideration. Companies may request grants slightly larger than the proposed caps, but are advised to discuss this with their federal program officer first.

Due to their smaller scope and greater time limitation, Phase I grants are designed to support the early stages of innovative research by encouraging applicants to obtain preliminary data for a subsequent Phase II application. These grants are suitable for small startup companies working with an academic entrepreneur who may have other teaching or administrative responsibilities and is not yet ready to devote 100% of their time toward the small business entity. Commonly funded projects in Phase I include: (1) pilot/feasibility studies, (2) secondary analysis of existing data, (3) development of research methodology, or (4) development of new research technology (Ford et al.).

Restrictions Accompanying Funding Grants

SBIR/STTR grants are accompanied by certain restrictions. Specifically, for the SBIR program, the PI must be employed mainly by the company, defined as devoting >50% of their effort to the company or project at the time of the grant. Applications with more than one principal investigator are allowed for SBIR grants, however, the small business must remain the primary employer of the contact PI. The STTR program is more flexible in comparison, placing no employment restrictions on the PI and mandating that more than 10% of their research effort is contributed to the company or project.

Subcontracts are permitted in the SBIR program but are limited to 33% of the budget in Phase I and 50% of the budget in Phase II applications. The STTR program requires a research partner institution that conducts more than 30% of the budgeted work, while the small business entity must be responsible for more than 40% of the work. Remaining funds from the STTR program may be allocated to the company, research partner, or consultants and subcontracts accordingly.

Seeking Outside Advice

Several sources of advice and guidance in preparing SBIR/STTR grants are available to academic entrepreneurs considering an SBIR/STTR application. Most university technology transfer offices have staff who are familiar with the SBIR/STTR process and can work with interested parties to put together an application. In addition, many state technology programs, through the Federal and State (FAST) Partnership Program, provide guidance to entrepreneurs in preparing SBIR/STTR applications (<https://www.sbir.gov/about-fast>).

First-time applicants are encouraged to find experienced mentors or grant consultants to answer questions and review their applications; often there are other academic faculty at the university who may have submitted SBIR/STTR grants in the past, and they can be a valuable resource (“Definitions of Criteria and Considerations for SBIR-STTR Critiques”). Private consultants are also available, and the typical cost is \$5,000–\$20,000, depending on their level of involvement.

NIH program staff members can and should also be contacted for advice and guidance; a list of funding priorities is available at <https://www.sbir.gov/sbirsearch/topic/current>. Primary contacts for SBIR/STTR program staff members at each institution offering funding can be obtained from the “SBIR/STTR Program Descriptions and Research Topics” web document (*Funding: NIH SBIR/STTR*). General information regarding previously awarded grants may also be accessible from federal agency websites—the NIH’s Computer Retrieval of Information on Scientific Projects (CRISP) database, for example, allows applicants to view basic features about current and past awarded grants, including the partnering institution, research area, and funded PI.

Obtaining examples of successful grant applications can provide valuable guidance for first-time applicants, but doing so requires a little more effort. Contacting the PI grantee directly for a copy is usually the quickest way to obtain successful examples, but copies of past funded grants can be obtained through the Freedom of Information Act by contacting the appropriate program officer (note that if you are submitting an SBIR/STTR grant, you can indicate on the application that you are submitting proprietary information in order to limit its release—this should be discussed with your federal program officer prior to submission). Federal agencies providing SBIR/STTR grant funding mechanisms may also have past examples of successful grant applications on their websites, and university-sponsored program offices may also provide access to repositories of previously funded SBIR/STTR applications from a particular institution.

Other university entities that commonly offer SBIR/STTR applicants assistance during the application process, apart from technology transfer offices, include programs that are involved with clinical and translational research. These and related offices often have staff that are familiar with the SBIR/STTR application process and can connect interested academic entrepreneurs with past applicants who have been successful at a particular institution. Large research-focused universities can often provide access to hospital electronic medical records or other types of data that can be drawn upon to provide preliminary results as part of an application, or proposed as a substrate for further SBIR/STTR research-related aims. University research administration offices may also serve important roles as advisors regarding potential conflicts of interest and can provide guidance for academic entrepreneurs seeking to navigate the differing research cultures between academia and industry. Finally, academic institutions frequently foster innovation centers or startup accelerators that may provide prospective academic entrepreneurs access to mentorship, networking opportunities, and other forms of guidance during the SBIR/STTR application process.

Conclusion

The SBIR/STTR grant mechanism represents both an important source of seed funding for small business entities in the United States involved in innovative technology development and a vehicle to facilitate greater cross-pollination and collaboration between academia and industry. The structure of SBIR/STTR grants is often ideal for academic entrepreneurs who have significant

experience planning and applying for traditional research grants and are also interested in exploring the broader commercialization potential of their work. The primary benefit of SBIR/STTR grants is that they are able to provide funding for academic entrepreneurs without the need for relinquishing equity in exchange. Compared to the traditional NIH academic grant mechanisms (R01/R21), SBIR/STTR grants are awarded to a greater proportion of applicants and can be more focused on the real-world implementation of new technology. From a small business perspective, the significant amount of time and effort invested in an application requires careful consideration of the potential pros and cons of investing the effort to apply for an award. Importantly, preliminary data or a working prototype can help an SBIR/STTR application, but ultimately the strength of the scientific idea and the team that is assembled are more important than either of the former, especially for Phase I applications. Grants consultants and university technology transfer offices are readily available to the interested applicant at most institutions, and first-time applicants are strongly encouraged to seek outside mentorship and support throughout the application process. As more and more businesses turn to industry-academia partnerships for innovation, the SBIR/STTR grant mechanism remains an important source of funding for developing and bringing new technologies to market.

Resources

1. SBIR/STTR On-Line Tutorials
 - a. The official Small Business Innovation Research Website produced tutorials designed to help interested parties learn more about the SBIR/STTR programs and application process. It provides an excellent overview of both programs and a guide for getting started with an application.
 - b. <https://www.sbir.gov/tutorials>.
2. NIH SBIR/STTR Application Process Infographic
 - a. The NIH website provides an interactive infographic that introduces interested parties to the process of applying for an SBIR/STTR grant.
 - b. <https://sbir.nih.gov/infographic>.
3. SBIR vs. STTR: Do You Really Understand the Differences?
 - a. Document from the University of Albany providing a high-level overview of basic differences between the SBIR and STTR programs and advice for the interested applicant on how to decide which program is most appropriate.
 - b. https://www.albany.edu/research/assets/The_difference_between_STTR_and_SBI_R.pdf.
4. Winning SBIR/STTR Grants: A Ten Week Plan for Preparing Your NIH Phase I Application
 - a. Garland, Eva R. *Winning SBIR/STTR Grants: A Ten Week Plan for Preparing Your NIH Phase I Application*. CreateSpace Independent Publishing Platform, 2014.
 - b. Excellent resource and guide for preparing SBIR/STTR grants.

- c. <https://www.amazon.com/Winning-SBIR-STTR-Grants-Application/dp/1494784440>.
5. Guide to SBIR/STTR Program Eligibility
- a. A document giving in-depth information regarding how to determine your eligibility for receiving SBIR/STTR grants. Helpful for determining SBIR/STTR grant eligibility.
 - b. https://www.sbir.gov/sites/default/files/elig_size_compliance_guide.pdf.

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