

Translational Research: How to Win SBIR/STTR Grants



Scientists acquire entrepreneurial skills and experience as they translate discoveries from the research bench to the bedside of a patient through successful academic-industry partnerships. The right collaboration can link someone with a promising idea to a winning team of researchers and business people to develop a viable product or service for the marketplace.

Entrepreneur Rick Morris secured a [Small Business Innovation Research](#) (SBIR) grant from the National Institutes of Health (NIH) in September, crediting his success to his collaboration with UT Health San Antonio clinician-scientists, [Sudha Seshadri](#), M.D., and [Carlos Jaramillo](#), M.D., Ph.D.

Morris is an experienced entrepreneur in the digital healthcare sector who moved to San Antonio from California in 2015. Morris's company [GaitIQ](#) is developing a software diagnostic tool for primary care providers to analyze gait patterns during an office appointment. The cloud-based software platform leverages machine learning, big data analytics, and artificial intelligence to detect subtle changes in the walking pattern of patients at risk of developing dementia. GaitIQ's approach uses a web camera in the doctor's office to capture patient videos that are analyzed in the cloud in less than five minutes. Currently, it takes three trained technicians and hours to capture and analyze someone's walk in a specialized gait lab at the cost of up to \$2,000, according to Morris.

"My attendance at networking events sponsored by the Office of the VPR facilitated introductions to Dr. [Joe Schmelz](#), Dr. [Kimberly Summers](#), and [Meyad Baghezza](#)," Morris said. "They trained the GaitIQ team on how to prepare a well-written proposal that yielded a timely IRB review."

Morris touts the value of seeking non-dilutive funding from the NIH SBIR program and the competitive scientific review process. "SBIR grants are hard to get," Morris said. "It helps to know how to approach the grant process for a successful outcome."

To Which Program Should I Apply—SBIR or STTR?

The first step is choosing the appropriate program because there are distinct [differences](#) between the SBIR and the [Small Business Technology Transfer](#) (STTR) programs.

SBIR awards are valuable sources of startup financing for very early idea-stage entrepreneurs working on a new product with high upfront development costs. Designed to support federal research and development (R&D) with high potential for commercialization, SBIR funding can help underwrite proof-of-concept research, which is needed before risk-averse private investors inject funding into an innovative product.

In contrast, STTR grants require the small business applying for the grant to collaborate with a nonprofit research institution. The intellectual property rights are negotiated in a licensing agreement between the nonprofit and the small business before the product goes into the market.

UT Health San Antonio researcher [James Lechleiter](#), Ph.D., professor of cell systems and anatomy, has used STTR funding to develop a therapeutic based on his research discovery that astrocytes could protect the brain after a traumatic brain injury. However, Dr. Lechleiter had trouble finding a company interested in commercializing this therapeutic treatment.

"I told Bill Korinek, a vice president for Pfizer at the time, of my difficulties," Dr. Lechleiter said. "Bill suggested instead that I start a new company."

The two co-founded Astrocyte Pharmaceuticals, which is commercializing the treatment for the market. The company has a [worldwide licensing agreement](#) with UT Health San Antonio for the exclusive use of patent rights owned by The University of Texas System Board of Regents and developed by Lechleiter.

Although both SBIR and STTR grants focus on developing innovative solutions to pressing problems that can then be commercialized for the market, Morris stresses that the two programs are not interchangeable.

SBIR grants are awarded to a small business that has the option to collaborate with research faculty to develop the proof of concept. The primary investigator (PI) must be employed by the small business, meaning the researcher cannot work full time elsewhere during the project period. The STTR mechanism allows the PI to be primarily employed at either the research institution or the small business.

Another important difference is how the award funding is allocated. STTR grants (both Phases I and II) require that the partnering research institute performs 30 percent of the work, with the small business responsible for 40 percent. The remaining 30 percent of the work can be allocated to the small business, the partnering institute, or to a third party subcontractor. In SBIR Phase I grants, the company must conduct 66 percent of the research, with only 33 percent available for research partners and subcontractors. For SBIR Phase II grants, the subcontracting limit increases to 50 percent.

Also, a higher number of federal agencies participate in the SBIR versus STTR program (11 versus 5).

Because both grant mechanisms are competitive and rigorously reviewed this type of funding can be a powerful signal for potential investors. "Obtaining STTR grant funding is getting a peer-reviewed stamp of approval from an investor's standpoint," said Dr. Lechleiter.

The choice between applying for an SBIR or STTR grant should also include considerations about the best way to get the product or service to market successfully.

"Collaborators must remember NIH's goal for SBIR grantees—the viable business should be able to attract private investment after a Phase II grant," Morris said. "Consider IP and licensing agreements carefully when thinking about how these can impact the company's profit and fundraising over the long term."

Collaboration Equals Better "Team Science"

The GaitIQ team advised their researchers to seek collaborators as a key factor in securing funding, build the best team to address the problem that they were trying to solve and view collaboration as a building block of one's scientific career.

"Nearly all SBIR/STTR awards require a multidisciplinary collaboration," said Eva Garland, Ph.D., CEO of Eva Garland Consulting (EGC), a firm that advises clients on strategies for planning, writing, and managing SBIR/STTR grants. EGC has worked with GaitIQ on their grants submissions and helped Astrocyte prepare three successful SBIR/STTR applications.

Dr. Seshadri is the founding director of the [Glenn Biggs Institute for Alzheimer's and Neurodegenerative Diseases](#) and a consultant for GaitIQ. She saw how a non-invasive, easy diagnostic tool to detect gait changes could be important in uncovering early markers for clinically diagnosed dementia. Dr. Seshadri emphasized how essential the "right collaborative partnerships are for better commercialization."

"My role is to help validate the software in a clinical setting and identify potential users for the tool to assure market acceptance," Dr. Seshadri said.

Dr. Jaramillo, assistant professor and director of clinical research at [San Antonio's Polytrauma Rehabilitation Center](#) at South Texas Veterans Health Care System, will serve as the PI for the human study testing the diagnostic tool. As a clinician-scientist, Dr. Jaramillo said that this “team science” approach complemented his research portfolio.

“Trying to write a grant on your own or with one other person is extremely time-consuming,” Jaramillo said. “Doing it collaboratively brings in expertise from different fields to strengthen the proposal to be submitted.”

Dr. Jaramillo advises junior researchers to view collaboration as a way to build “bridge networks” where work on one small grant may lead to related work on larger ones. “Being a co-investigator or a consultant on a couple of grants here and there can help lead you to be the principal PI on a grant later,” Dr. Jaramillo said.

Dr. Lechleiter agrees that researchers can learn a great deal from collaborations, especially when they lead to the commercialization of discoveries. “I think there’s an ongoing educational process for scientists on how to approach these grants,” Dr. Lechleiter said. “We have to learn how to develop translational research for the market.”

SBIR/STTR Priorities and Program Officers’ Insights

The third tip is to make sure your research addresses a problem on the SBIR/STTR priority list of topics of interest. When applying for a SBIR grant, your impact score is computed based on the problem you’re solving, why is it worth solving, and the competitive market for existing research, as well as, competing solutions already available.

“Their research topics list is a ‘blinking green light’ of what these agencies are interested in and want to fund,” Morris said. “What you’re doing as a science entrepreneur is looking for problems that require research for a viable solution.”

Funding limits on the federal awards are set at \$150,000, up to \$225,000 for a phase I grant. However, completing all phase I milestones could lead to a phase II application that could be funded up to \$3,000,000, according to Dr. Lechleiter. A special category of research topics applicable only to NIH has a budget waiver for awards above these limits. A complete list of the 2018 SBIR and STTR NIH research award topics over statutory budget limitations can be found [here](#). The range for these SBIR/STTR phase I grants can be anywhere from \$150,000 to \$700,000.

“Multidisciplinary collaboration can make a big difference when it comes to securing grant funding,” Garland said.

Dr. Jaramillo also recommends talking to the appropriate program officer to solicit feedback on your concept. Researchers may email an executive summary to an SBIR/STTR program director to help gauge whether a project meets the program’s intellectual merit and commercial impact criteria. A list of all program directors and their contact information can be found [here](#).

“Reaching out to them has always been encouraged,” Dr. Jaramillo said. “Their feedback can help you tailor your grant submission and stay true to what you’re trying to do.”

The GaitIQ team is cautiously optimistic about the ability to detect changes in gait a decade or more before the obvious onset of dementia symptoms. “Using technology to develop a consistent methodology and precise measurements of gait in 3-D will give doctors an accessible diagnostic to use with their patients for early warning and intervention,” Morris said. “The NIH grant is an important first step in validating our approach to the problem we’re solving.”

Remember, federal funding can be powerful evidence for venture capitalists that your proposed solution has scientific merit. “The rigor of getting an SBIR grant means there’s a higher chance the product will get to the market,” Dr. Seshadri said. “For investors, it’s a vote of confidence.”

Sidebar:

[GrantSeekers](#) is a service under the auspices of the Vice President for Research (VPR) lead by [Sunil Ahuja](#), M.D. and Director of Research Enhancement Programs. This service provides valuable feedback to researchers' grant applications via a rigorous internal and external peer review process.



(l-r) Rick Morris; Sudha Seshadri, M.D.;
James Lechleiter, Ph.D.; Carlos Jaramillo, M.D., Ph.D.