

# America's Seed Fund: Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Programs Grow Results

## Executive Summary

The federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs offer a lifeline to small medical device technology companies that otherwise would not be able to secure the initial funding necessary for expensive research and development. The programs support scientific development and product innovation benefiting patients in need and the public at large. They also spur growth in the U.S. and local economies by helping small businesses implement their groundbreaking ideas. The authorization for these initiatives is set to expire September 30, 2022.

## About "America's Seed Fund"

Since 1982, a bipartisan Congress has authorized start-up grants to help entrepreneurs transform their ideas from concept to reality. Innovations to save lives, protect military personnel, safeguard the national power grid, and much more have earned critical early funding from what is called America's Seed Fund.

The SBIR/STTR programs offer highly competitive grants across 11 federal agencies, from the National Science Foundation to the Department of Defense.

Over 40 years, these programs have provided more than 179,000 awards, totaling more than \$54.3 billion, to U.S. small businesses. The programs stimulate entrepreneurship to meet key government research and development needs. The resulting innovations routinely lead to public benefit because the startups have a high commercial success rate, per a National Academy of Sciences study.

Participating businesses must be U.S.-based, fostering domestic innovation. Women and socially or economically disadvantaged persons are encouraged to participate. Rigorous peer review, a competitive process, and partnerships with academic research institutions provide the scientific rigor needed to secure the proof of concept that eventually will attract private investment.

Grant recipients build out their businesses, spin off new companies, license their technology to others, and develop new products. The economic impact is tremendous.

A 2018 study of the National Cancer Institute's SBIR program found that \$787 million in Phase II awards generated \$26.1 billion in total economic output, 107,918 jobs, and \$2.93 billion in tax revenue. It also demonstrated that 65 percent of the awards funded the development of a new treatment for a group of patients who lacked a treatment option. The 444 companies supported by these Phase II awards reported raising a total of \$4.25 billion in total outside investment funding following their awards. 89 percent of these companies indicated that the SBIR funding came at a pivotal or critical moment for the small business.<sup>1</sup>

## The Impact on Medical Device Start-ups

Medical technology device development relies on lengthy research and testing. Devices must meet a high bar for safety and effectiveness. Start-ups consisting of a handful of employees cannot sustain paying for months and even years of research and development, and private investors are reluctant to fund testing that might not result in a quickly profitable product. Investors also consider market share and scalability. A product that makes a difference to thousands of patients still might not be attractive enough to investors.

75 percent of AdvaMed's 450 members are small companies. Many of them are members of AdvaMed Accel, an initiative for start-ups. In a 2021 survey, 89 percent of Accel respondents reported having applied for SBIR/STTR grants; 31 percent of their applications were rewarded. Respondents said:

- *"Receiving our Phase 1, Phase II and IIB awards from the National Science Foundation all led to additional equity financing rounds."*
- *"It was pivotal to our survival...the FastTrack grant paid our salaries while we closed our Series A2 round."*
- *"This capital has helped us with credibility and with taking our high-risk projects further."*

Actuated Medical, an Accel member in central Pennsylvania, twice earned the prestigious Small Business Administration Tibbetts Award for SBIR Excellence, in 2020 and 2014.

The SBIR/STTR programs are critical to the company's developing medical devices that improve patient outcomes and reduce health care costs. Actuated Medical's TubeClear device clears clogs from the feeding tubes that deliver food, hydration, and medicine to critically ill patients. Tube clogging is common, disruptive for patients, and a constant source of worry for health care providers. Even though a tube clearing device is invaluable to those who need it, investors considered the early product market too small for their time and money. SBIR/STTR funding helped Actuated Medical develop the TubeClear system, now providing care to critically ill patients nationwide.

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<sup>1</sup> [https://sbir.cancer.gov/sites/default/files/documents/NCI\\_SBIR\\_ImpactStudy\\_2pager.pdf](https://sbir.cancer.gov/sites/default/files/documents/NCI_SBIR_ImpactStudy_2pager.pdf)

The first patient to use the TubeClear system was a 27-year-old soldier in intensive care at Walter Reed hospital in Washington, D.C. The device cleared his tube, delighting his health care team in working efficiently without causing him discomfort.

## **Conclusion**

Congress has the opportunity to maintain or enhance the successful SBIR/STTR programs for small businesses nationwide. Program funding is already part of the participating agencies' budgets. Congress needs only to re-authorize the programs rather than appropriate additional funding for them. Timely re-authorizing the SBIR/STTR programs would assure the participating federal agencies, small businesses, and academic institutions of a consistent source of funding to drive the research and development essential to America's long-term economic growth and national security. These programs are key to promoting the innovations and advancing the development of new treatments to help patients nationwide.