Congressionally Mandated Assessment of the SBIR and STTR Programs at the National Institutes of Health, 2019

March 11, 2020

Keck Center of the National Academies

National Institutes of Health
Office of Extramural Research

Task Leaders

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Task 1: Proposal Strengthening

- Work in consultation with NIH (and NIH designees) to ensure alignment of detailed work plan with the subsequent tasks and to ensure that the deliverables will directly address the needs of NIH and the congressionally mandated reporting requirements.

Task 2a: SBIR Effectiveness

- Build upon the 2015 NASEM study of the NIH SBIR program, in collaboration with SEED and leveraging existing NIH evaluation strategies and data.
- As needed and in collaboration with appropriate parties, develop survey instruments and conduct surveys and case studies of SBIR awardees, as well as updating previously collected information as necessary for outcomes information.
- The study will focus on how the NIH SBIR program has fulfilled the requirements of the enabling legislation.

Task 2b: SBIR Effectiveness

- Study the impact and effectiveness of the enabling strategies NIH has employed to enhance the program, including technical and business assistance programs and other NIH central and IC enabling strategies as described by NIH and agreed upon by NASEM.

- ❑ Phase IIB
- ❑ Direct to Phase II
- ❑ Fast Track
- ❑ Commercialization Readiness Pilot Program
- ❑ Niche Assessment Program
- ❑ Commercialization Accelerator Program
- ❑ I-Corps
- ❑ C3i
- ❑ Applicant Assistance Program
- ❑ Entrepreneurs-in-Residence?
- ❑ Regulatory support?
- ❑ Company showcase support?

Task 3a: STTR Effectiveness

- Conduct a comprehensive study of how the STTR program, including the strategies designed to enable academic entrepreneurship and innovation, has fulfilled the requirements of the enabling legislation, in collaboration with SEED and leveraging existing NIH evaluation strategies and data. The study shall include:

Task 3a: STTR Effectiveness

1. A review of the collaborations created between small businesses and research institutions, including an evaluation of the effectiveness of the program in stimulating new collaborations and any obstacles that may prevent or inhibit the creation of such collaborations.
2. An evaluation of the effectiveness of the program at transferring federally funded technology and capabilities toward commercialization.
3. Examine the non-economic impacts to businesses including measures of demographics, participation of underrepresented groups, and knowledge of the technical and business requirements of life science sector commercialization.
4. An analysis of whether STTR funds could be employed more effectively by the NIH STTR program to achieve the goals of the enabling legislation.

Task 4a: Economic and Healthcare Impact

- Examine the regional economic impacts associated with NIH SBIR and STTR programs, including relevant measures such as firm survival, direct and indirect employment effects, business revenues, and gross value added.

Task 4b: Economic and Healthcare Impact

- Assess the contribution of the NIH SBIR and STTR programs to regional economic development programs and strategies, including those around inclusivity and workforce development.

Task 4c: Economic and Healthcare Impact

- Assess healthcare impacts of the NIH SBIR and STTR programs. Include an assessment of the relationship between technology outcomes supported by NIH SBIR and STTR programs and commercially available healthcare products and services.

Deliverables

- A **Final Report** shall be provided that includes the findings and recommendations resulting from all three tasks included above. It must **address NIH accomplishments**, **challenges that NIH faces, as well as possible solutions to the challenges**. Deliverables could also include **summary data and analysis of commercialization rates, sources of follow-on funding, case study reports, survey tools/instruments**, as well as other agreed upon materials.
- Quarterly progress summaries are also required as per the umbrella contract.

Committee's Methodology May Include

- Attempting to determine what information in the application may be predictive of successful outcomes and the ability to attract additional investment (characteristics considered may include firm age, firm size, corporate structure, lineage of founders, age of founders, number of founders, level of founder effort committed to company, and other relevant factors); and attempting to determine which metric is the strongest predictor of successful commercialization;
- Examining specific characteristics that impact the time required to observe measurable outcomes, such as company formation, patenting activity, revenue, job creation, and other relevant, observable activities; and providing analysis on the time required to achieve specific measurable outcomes for all relevant productivity metrics; and
- Assessing the efficacy of post-award assistance (to include mentoring and coaching by NIH staff), including developing metrics to assess impact and gain an understanding of whether these activities result in increases in follow-on funding or revenue-producing commercialization outcomes.
- To the extent that data are provided, the committee may also analyze information to determine if certain characteristics of reviewers (such as whether the reviewer has experience in industry or with start ups) are positively correlated with better predictions of commercial success.
- An analysis of the geographic dispersion of research institutions associated with small businesses receiving STTR awards, and a comparison of demographic differences among small business owners to help determine whether or not there are any obstacles inhibiting or preventing the creation of such collaborations.