

NCI SBIR INFORMATION FOR YALE FACULTY AND SMALL BUSINESSES ATTENDING THE YALE INNOVATION SUMMIT

The National Cancer Institute (NCI) SBIR/STTR Development Center (<https://sbir.cancer.gov/about>) provides federal funding and resources to startups working on anti-cancer technologies including therapeutics, diagnostics, devices, radiation therapy and imaging, research tools, and digital health. The program's budget has now grown to ~\$180M a year, and we fund ~250-300 companies at any given time.

We have separate SBIR and STTR research funding programs for eligible small business concerns, with 3 application deadlines per year (January 5, April 5, and September 5). For reference, see the current NIH Omnibus SBIR solicitation <https://grants.nih.gov/grants/guide/pa-files/PA-18-574.html>; and the current NIH Omnibus STTR solicitation <https://grants.nih.gov/grants/guide/pa-files/PA-18-575.html>. Both solicitations will be renewed (republished) in 2019 shortly after the April 5 receipt date (April-May timeframe). The STTR mechanism requires a university research partner and for the former this is optional. In addition, for STTR the PI can be an employee of the university even though the award is formally made to the small business. Depending on the stage of development, small businesses can sequentially apply for Phase I awards at \$400K total costs maximum for 1 year, Phase II awards at \$2.0 Million maximum for 2-3 years, and a Phase IIB Bridge award (SBIR only) at \$4.0 Million maximum for 3 years from NCI, and with the expectation of at least a 1:1 match of funds from a non-federal government source that is completely independent of the company. In addition, for technologies at an advanced stage of development as reflected by a large body of preliminary data, companies can apply for both Phase I and Phase II funding within one application (Fast-Track mechanism), or apply for a Direct-to-Phase II award. We also offer SBIR contract awards in narrowly focused technical areas. 10-20 topics are published in July-August, and there is one application deadline per year, typically in October. For grants or contracts, Phase I projects are considered small scale feasibility/demonstration studies, whereas Phase II projects are meant to cover most pre-IND/IDE/510K activities, ideally culminating in a regulatory submission to FDA at the end. Phase IIB projects can cover additional needed pre-IND/IDE/510K activities, and/or clinical trials (Phases I-II primarily, and rarely Phase III).

In addition to research funding (non-dilutive capital), NCI also provides mentorship and other commercialization resources to the small businesses it funds through the SBIR and STTR programs. NCI provides an extensive suite of commercialization resources including entrepreneurship training (e.g. the NIH I-Corps program [<https://grants.nih.gov/grants/guide/pa-files/PA-19-029.html>]), commercialization workshops, and the Investor Initiatives Program wherein funded companies submit business plans and compete to win paid trips to investor conferences in order to give pitches and hopefully raise capital. We also have an Applicant Assistance Program for new applicants, and a Peer Learning and Networking (PLAN) Webinar Series for current awardees. The NCI SBIR program will also be launching a Peer-to-Peer Mentoring program, and an NCI SBIR FDA Regulatory Assistance program in the near future. In addition to these NCI programs, the NIH SBIR program offers the Niche Assessment Program and Commercialization Accelerator Program (CAP). For further details on NCI commercialization assistance programs, see <https://sbir.cancer.gov/programseducation>. For related NIH programs, see <https://sbir.nih.gov/tap>.

Two NCI SBIR staff will be attending the 2019 Yale Innovation Summit, and we are interested in meeting with any Yale or small business staff who wish to pursue SBIR/STTR research funding. We can provide advice on how to prepare competitive funding applications. Our contact information is listed below.

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