SBIR·STTR
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COURSE 2, TUTORIAL 5

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

The combined SBIR and STTR budget across all of the participating agencies is approximately $2.5 billion dollars. Of that, a little over half was provided to small businesses in the form of contracts, while the other half was provided as grants. What's the significance of this? Why should you care if some agencies provide contracts and others provide grants? Contracts have a very specific deliverable, while grants are much more open-ended. Agencies that engage in basic research, such as the Department of Health and Human Services, tend to provide grants, which provide considerable latitude to applicants in defining research problems of interest.

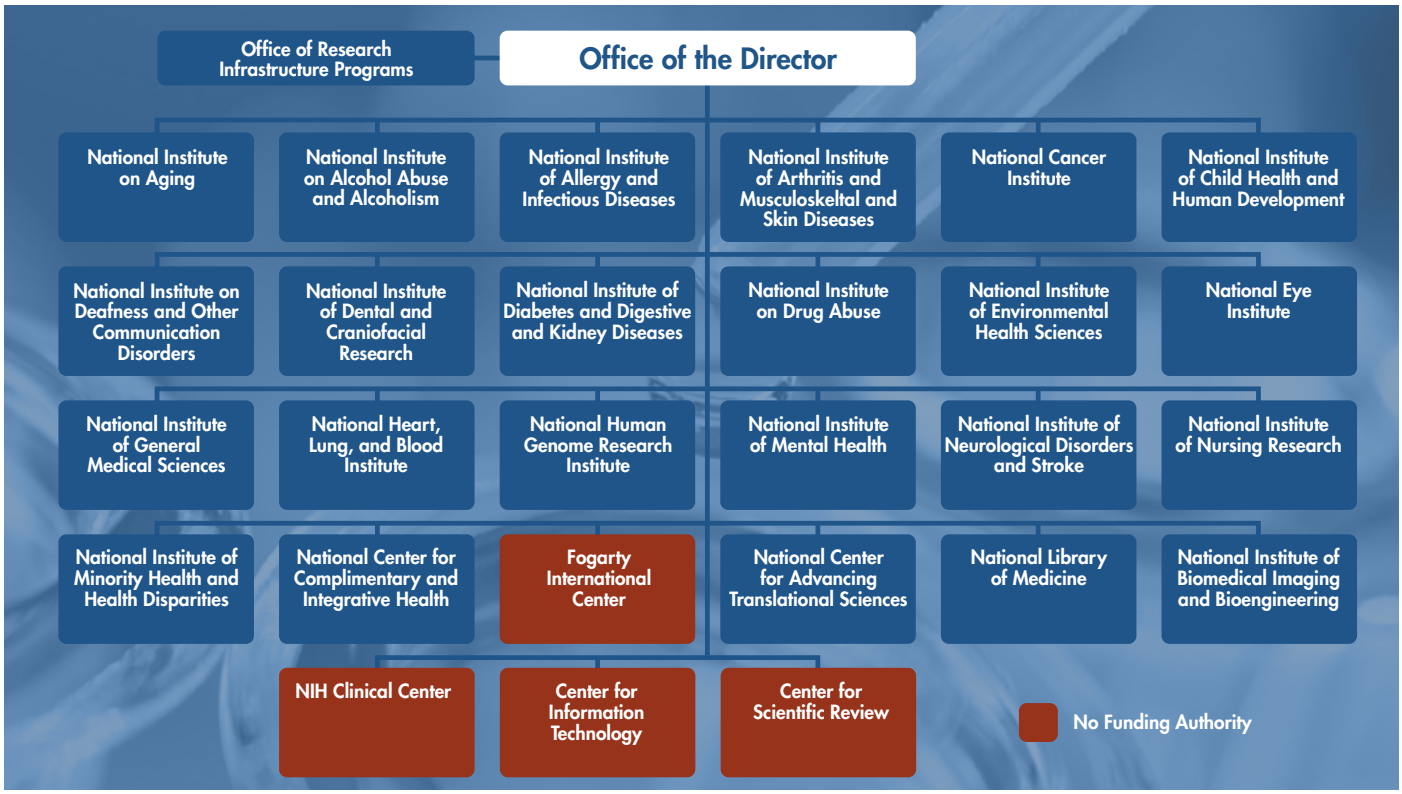
The Department of Health and Human Services, or HHS, actually provides both grants and contracts, with the preponderance of its awards being made as grants. The National Institutes of Health, or NIH, is the largest granting institution participating in the SBIR/STTR program and is the largest component within HHS. Given the size of the NIH program, which has roughly 90-95% of the HHS SBIR budget, you often hear people speak only about the NIH program.

The mission of National Institutes of Health is very broad and includes the application of knowledge to enhance health, lengthen life, and reduce illness and disability. The National Institutes of Health include 27 Institutes and Centers, referred to as ICs. Twenty-three of these provide SBIR or STTR awards. However, there are four organizations that do not have the funding authority to participate in these programs. The SBIR Program Office is located in the Office of the Director. However, each participating IC also has its own SBIR/STTR point of contact.

If we look at the budget of the NIH Institutes and Centers, you find tremendous variability in the size of their budgets. The institute with the largest budget is the National Cancer Institute, or NCI, followed by the National Institute of Allergies and Infectious Diseases (NIAID), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of General Medical Sciences (NIGMS).

FUNDING OPPORTUNITY ANNOUNCEMENTS (FOA)

NIH refers to its solicitations as Funding Opportunity Announcements, or FOA. The NIH SBIR and STTR programs commonly use what is referred to as Parent funding opportunity announcements, also known as Omnibus solicitations, which allow applicants to submit investigator-initiated projects for consideration by any of the 23 NIH Institutes and Centers (ICs), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA). The Omnibus is released once a year and allows three occasions when an applicant



Omnibus vs. Targeted FOAs

	Omnibus	Targeted
Due Dates	Standard Due Dates • Cycle 1: September 5 • Cycle 2: January 5 • Cycle 3: April 5	Standard or Customized Due Dates
Review	SBIR/STTR Panels at CSR	SBIR/STTR panels at CSR or SBIR/STTR panel at Institute/Center
Application Instructions	Follow SF424 R&R SBIR/ STTR Application Guide & Annotated Form Set	Follow SF424 R&R SBIR/ STTR Application Guide & Annotated Form Set and any additional instructions in FOA

may submit a proposal in response to a topic in the omnibus solicitation. This practice is unique to HHS, as most agencies allow one opportunity to respond to a specific solicitation. In response to the FOA released in June, 2017, applicants may submit proposals on September 5th, 2017; January 5th, 2018, and April 5th, 2018. Examples of some of the topic areas that you will find in the FOA include biosensors, telehealth, nuclear medicine, proteomics, and chronic symptom

The Likelihood of Winning an Award

Fiscal Year	SBIR/STTR	Phase	Numbers of Applications Reviewed	Numbers of Applications Awarded	Win Rate	Total Funding
2015	SBIR	Fast Track	337	66	19.6%	$18,157,545
2015	SBIR	Phase I	3,425	514	15.0%	$117,110,555
2015	SBIR	Phase II	823	241	29.3%	$179,946,727
2015	STTR	Fast Track	61	10	16.4%	$2,171,909
2015	STTR	Phase I	911	149	16.4%	$33,782,224
2015	STTR	Phase II	87	31	35.6%	$21,597,183
2015	**FY TOTAL**		**5,644**	**1,011**	**17.9%**	**$372,766,143**
2016	SBIR	Fast Track	512	67	13.1%	$17,348,139
2016	SBIR	Phase I	4178	526	12.6%	$121,272,849
2016	SBIR	Phase II	1,194	299	25%	$240,205,168
2016	STTR	Fast Track	109	16	14.7%	$4,866,290
2016	STTR	Phase I	1,341	191	14.2%	$44,316,736
2016	STTR	Phase II	121	38	31.4%	$29,964,963
2016	**FY TOTAL**		**7,522**	**1,152**	**15.3%**	**$467,109,646**

management, to name a few. Please note that it is recommended that you always contact the IC Program Manager before submitting an application. This is considered critical for success. In addition to the Omnibus solicitation, the NIH Institutes and Centers also issue targeted funding opportunity announcements for certain research areas, as well as an annual NIH SBIR contract solicitation.

AWARD SIZES

Phase I SBIR and STTR awards are typically for $150,000. However, the Reauthorization Act of 2011 allowed for a hard cap of $225,000 for Phase I and $1.5M for Phase II. As the development of medical technologies is known to be very expensive, proposers that can justify the need for more funds may apply for a waiver from SBA to go above this hard cap. In addition, SBA recently has approved a specific list of topics which are approved to exceed these caps. Another change brought about by the most recent reauthorization is the eligibility of small business concerns that are majority-owned by multiple venture capital operation companies, hedge funds, and private equity firms. Previously this was not allowed.

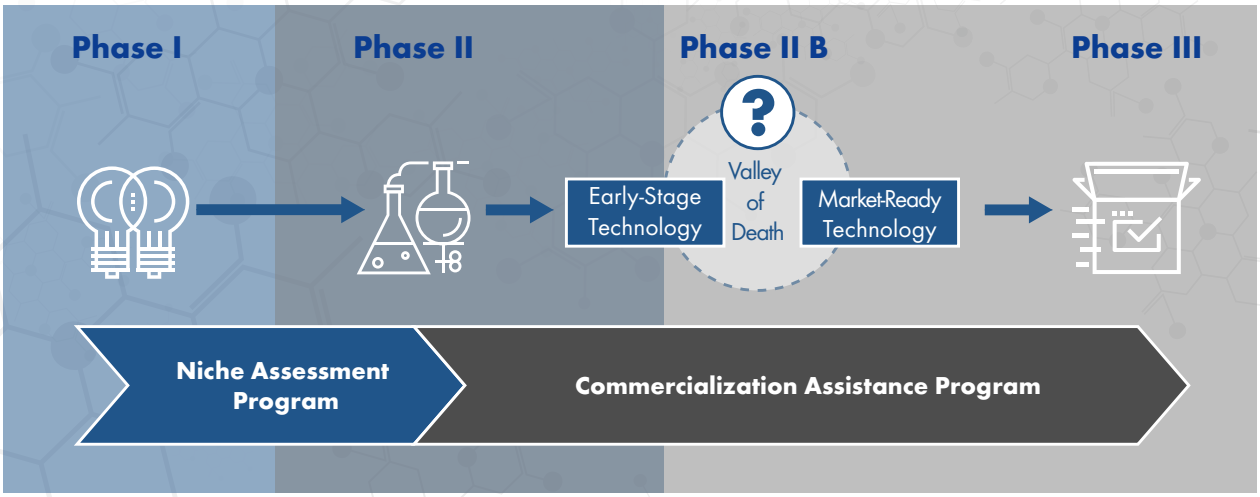
THE LIKELIHOOD OF WINNING AN AWARD

What is the likelihood of winning a Phase I SBIR or STTR award from NIH? The accompanying table shows the likelihood of winning a Phase I, Phase II, or Fast-Track award from NIH in 2015 and 2016. Fast-Track, by the way refers to submitting a Phase I and Phase II application concurrently, as a means of decreasing the delay between Phase I and Phase II awards. In looking at 2016, you see that NIH received 4,178 SBIR Phase I proposals and made phase I awards to 12.6% of the applicants or 526 projects. With respect to STTR Phase I applicants, 1,341 proposals were submitted and 14.2% of the applicants received an award.

The review process of SBIR and STTR applications is unique and involves initial review by the NIH Center for Scientific Review which assigns the application to an IC and IRG. After the IC staff prepares a funding plan for the IC director, the application is then sent to the Advisory Council or Board, which recommends approval. Please be sure to consult the webinars that are referenced in the tools section of this tutorial in order to learn more about the review process.

NIH does many things in an effort to move technologies forward. A relatively new initiative is the Phase IIB program, which is a sequential Phase II award. This allows a project to receive an additional $1 million a year for up to 3 years on a specific project. There is a Competing Renewal Application process for Phase IIB awards. NIH has also implemented most of the new initiatives allowed by the most recent reauthorization. This includes the ability to shift from an SBIR to an STTR award, or from an STTR to and SBIR award, when going from Phase I to Phase II.

Helping Companies cross the "Valley of Death"



It should be noted that the Congressional authority for two pilot programs has expired. Therefore, at this time, HHS does not have a Direct-to-Phase II pilot program or a Commercialization Readiness pilot program.

HHS, however, has two technical assistance programs provided to HHS awardees. The Niche Assessment Program is offered by Foresight S&T to Phase I awardees. This program identifies other potential uses of the technology, determines the com- petitive advantage, and market entry strategies. For Phase II awardees another service provided by LARTA is called the Commercialization Accelerator Program or CAP. This program offers a menu of services including strategic/business planning, FDA requirements, technology valuation, manufacturing issues, and patent and licensing issues.

To learn more about the HHS SBIR and STTR programs, be sure to consult the NIH SBIR/STTR program website and don't hesitate to reach out to the various representatives of the SBIR and STTR program located at the Office of the Director or to the points of contact within the individual Institutes, Centers, or components. The SBIR/STTR application infographic provides a good high level overview of the NIH SBIR/ STTR programs.