

TUTORIAL #9

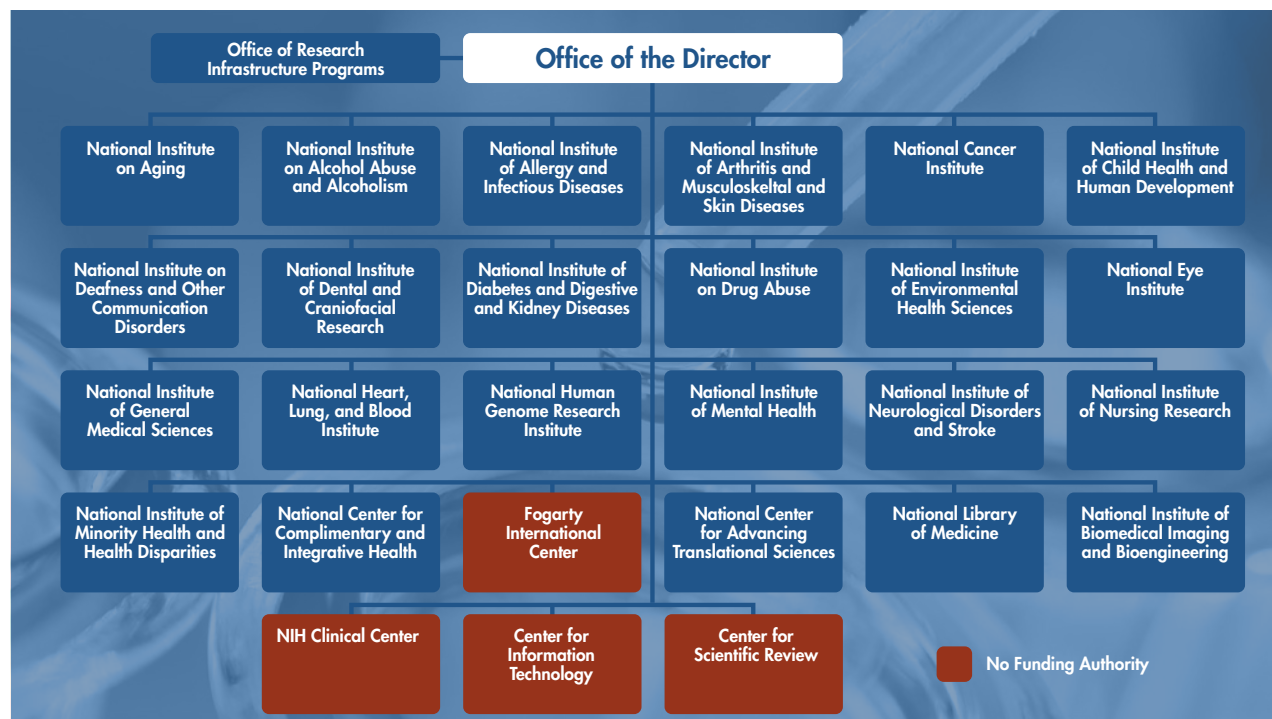
INDIVIDUAL AGENCY REQUIREMENTS DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)



In 2015 the combined SBIR and STTR budget across all of the participating agencies was \$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-four 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 Medicine (NIGMS).

NIH refers to its solicitations as Funding Opportunity Announcements or FOA. The NIH SBIR and STTR programs commonly use what is referred to as a parent funding opportunity announcements, also known as Omnibus solicitations, which allow applicants to submit investigator-initiated

projects for consideration by any of the NIH 24 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 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, 2015, applicants may submit proposals on September 5, 2015; January 5th, 2016, and April 5th, 2016. Examples of some of the topic areas that you will find in the FOA include biodefense biosensors, telehealth, proteomics, and imaging devices to name a few.

Omnibus vs. Targeted FOAs

	Omnibus	Targeted
Due Dates	Standard Due Dates <ul style="list-style-type: none"> • 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

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.

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.

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 2013 and 2014. 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 2014, you see that NIH received 3,622 proposals and made phase I awards to 18% of the applicants or 652 projects. With respect to STTR Phase I applicants, 788 proposals were submitted and 20.3% of the applicants received an award.

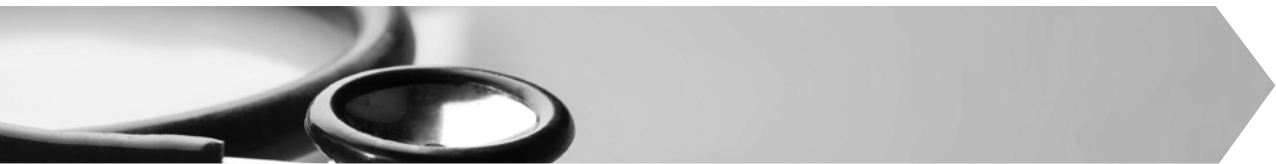
NIH-wide SBIR/STTR Win Rates 2013-2014

Fiscal Year	SBIR/STTR	Phase	Numbers of Applications Reviewed	Numbers of Applications Awarded	Win Rate	Total Funding
2013	SBIR	First Track	313	49	15.7%	\$13,981,386
2013	SBIR	Phase I	3,738	495	13.2%	\$114,040,157
2013	SBIR	Phase II	542	178	32.8%	\$136,348,846
2013	STTR	First Track	42	12	28.6%	\$2,542,128
2013	STTR	Phase I	583	109	18.7%	\$24,138,629
2013	STTR	Phase II	72	19	26.4%	\$10,985,373
2013	FY TOTAL		5,290	862	16.3%	\$302,036,519
2014	SBIR	First Track	328	71	21.6%	\$17,054,967
2014	SBIR	Phase I	3622	652	18.0%	\$144,793,079
2014	SBIR	Phase II	566	229	40.5%	\$170,387,226
2014	STTR	First Track	60	5	8.3%	\$1,082,086
2014	STTR	Phase I	788	160	20.3%	\$35,828,877
2014	STTR	Phase II	87	37	42.5%	\$22,182,184
2014	FY TOTAL		5,451	1,154	21.2%	\$391,328,419

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 sure to consult the webinars that are reference 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. NIH has also started a Direct to Phase II pilot Program which allows companies that have done the work typically associated with Phase I with non-SBIR funding to start engagement in the program SBIR program with a Phase II award. Being a pilot program the Direct to Phase II awards are authorized through 2017. At that time, with the next reauthorization the decision will be made about the continuation of this program.



is \$3 million over a three year period, but the participating Institutes and Centers vary greatly in the amount that each allows.

HHS also 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 competitive advantage, and market entry strategies. For Phase II awardees another service provided by LARTA is called the Commercialization Assistance 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.

Helping Companies cross the “Valley of Death”

The diagram illustrates the commercialization process across four phases:

- Phase I:** Represented by an icon of two lightbulbs, indicating the initial idea or invention stage.
- Phase II:** Represented by an icon of laboratory glassware (a flask and a beaker), indicating the early-stage technology development.
- Phase II B:** This phase is divided into two sub-steps: **Early-Stage Technology** and **MarketReady Technology**. A dashed circle with a question mark labeled **Valley of Death** spans the gap between these two sub-steps, representing the critical transition point.
- Phase III:** Represented by an icon of a document with a checkmark, indicating the final market-ready stage.

Supporting programs are shown at the bottom:

- Niche Assessment Program:** A blue arrow pointing right, spanning from Phase I to Phase II.
- Commercialization Assistance Program:** A dark grey arrow pointing right, spanning from Phase II to Phase III.

the SBIR and STTR program located at the Office of the Director or to the points of contact within the individual Institute, Centers, or components.