



*Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)*

NIH Small Business Programs (SBIR/STTR): Federal Funding for Biomedical Entrepreneurs

Kory Hallett, PhD

NCI SBIR Development Center

Stephanie Fertig, MBA

National Institute for Neurological Disorders and Stroke





Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

NIH/CDC Working Group for Women Owned, and Socially and Economically Disadvantaged Businesses

NATIONAL CANCER INSTITUTE (NCI) SBIR Development Center



Kory Hallett, PhD



Christie Canaria, PhD

NATIONAL INSTITUTE FOR NEUROLOGICAL DISORDERS AND STROKE (NINDS)



Stephanie Fertig, MBA



Rebecca Roof, PhD



John Sheridan, PhD

NATIONAL CENTER FOR COMPLIMENTARY AND INTEGRATIVE HEALTH (NCCIH)

Julia Berzhanskaya, PhD

NATIONAL INSTITUTES OF HEALTH

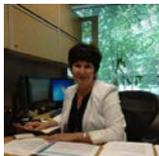


Betty Royster
SBIR/STTR Office



Miguel Contreras, PhD
Office of Research and Infrastructure Programs

NATIONAL INSTITUTE AGING AND INFECTIOUS DISEASE (NIAID)



Natalia Kruchinin, PhD



Timothy Hsiao, PhD

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

Derrick Tabor, PhD



NATIONAL HEART, LUNG AND BLOOD INSTITUTE (NHLBI)



Jennifer Shieh, PhD



Eric Padmore, PhD

Darlene Forrest, PhD



CENTERS FOR DISEASE™
CONTROL AND PREVENTION





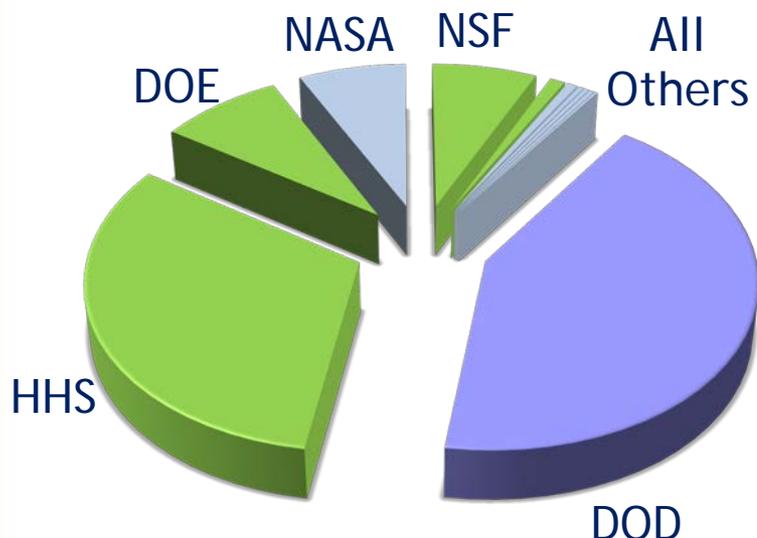
- **SBIR/STTR Program Overview**
- Program Eligibility
- NIH SBIR/STTR Program Specifics
- Solicitations and Funding Opportunities
- The NIH Peer-Review Process
- Transitioning to the Marketplace
- Question & Answer





Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR Budgets by Agency FY2015



**~ \$2.5B in FY15
across all agencies**

- Grants
- Contracts



Agencies with SBIR and STTR Programs	Budget
Department of Defense (DOD)	\$ 1.070 B
Department of Health and Human Services (HHS), including the National Institutes of Health (NIH)*	\$797.0 M
Department of Energy (DOE), including Advanced Research Projects Agency - Energy (ARPA-E)	\$206.1M
National Aeronautics and Space Administration (NASA)	\$ 180.1 M
National Science Foundation (NSF)	\$176.0 M
Agencies with SBIR Programs	Budget
U.S. Department of Agriculture (USDA)	\$25.3M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) and Domestic Nuclear Detection Office (DNDO)	\$17.7 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)*	\$8.4M
Department of Transportation (DOT)	\$7.9 M
Department of Education (ED)	\$7.5 M
Environmental Protection Agency (EPA)	\$4.2 M





SET ASIDE



(FY16)



(FY17)

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization



(FY16)



(FY17)

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization



2015 Budget	SBIR	STTR
NIH	\$691M	\$95M
CDC	\$7M	N/A
ACL (NIDILRR)	\$2.7M	N/A
FDA	\$1.45M	N/A
ACF	\$88K	N/A

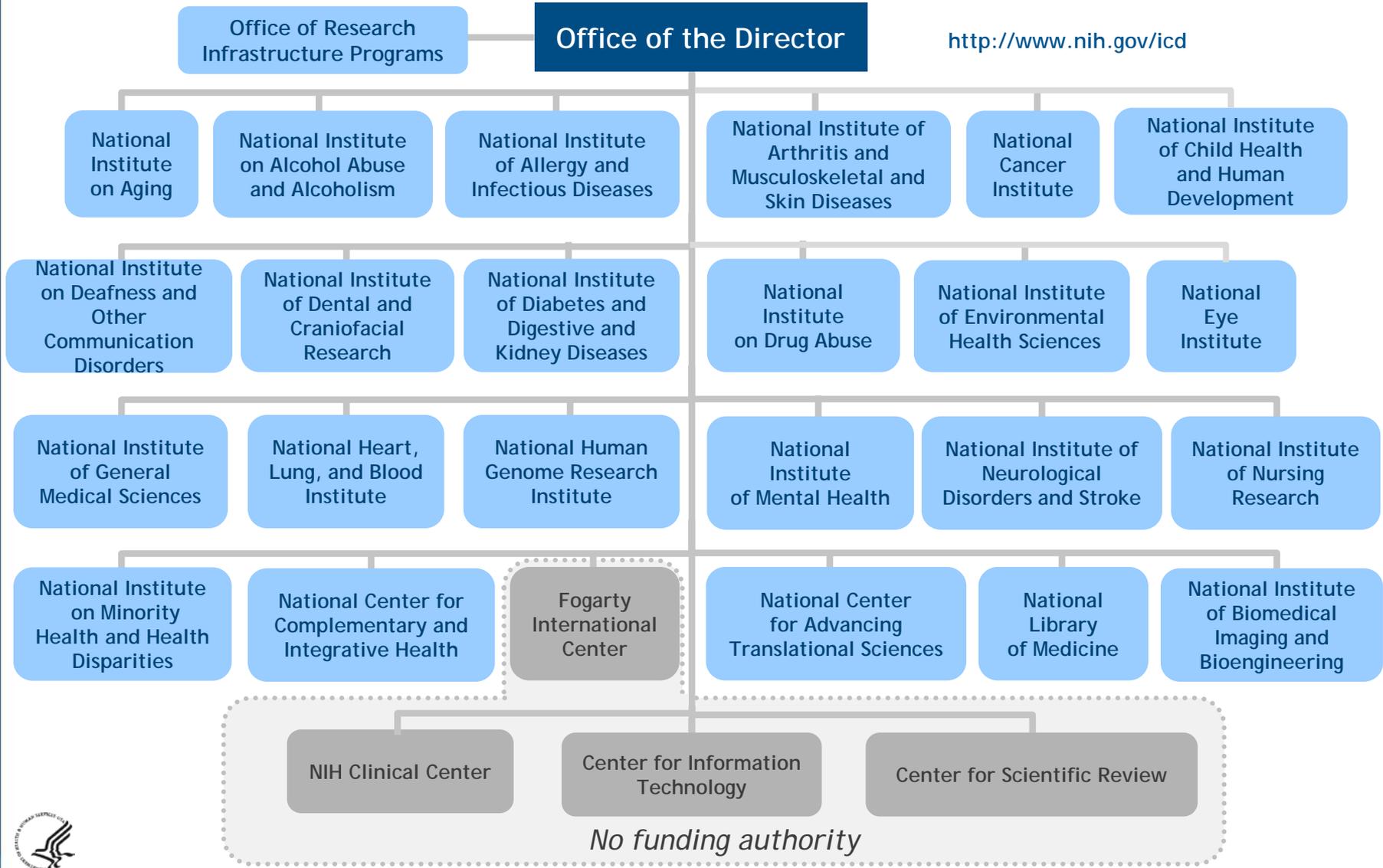


*To seek fundamental knowledge about the nature and behavior of living systems and the **application of that knowledge to enhance health, lengthen life, and reduce illness and disability.***



Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

National Institutes of Health



*Discovery*Phase
I

Phase I Feasibility Study

Budget Guide: \$150K for SBIR and STTR

Project Period: 6 months (SBIR); 1 year (STTR)

*Development*Phase
II

Phase II Full Research/R&D

\$1M for SBIR and STTR, over two years

Phase
IIB

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/to FDA

Many, but not all, IC's participate

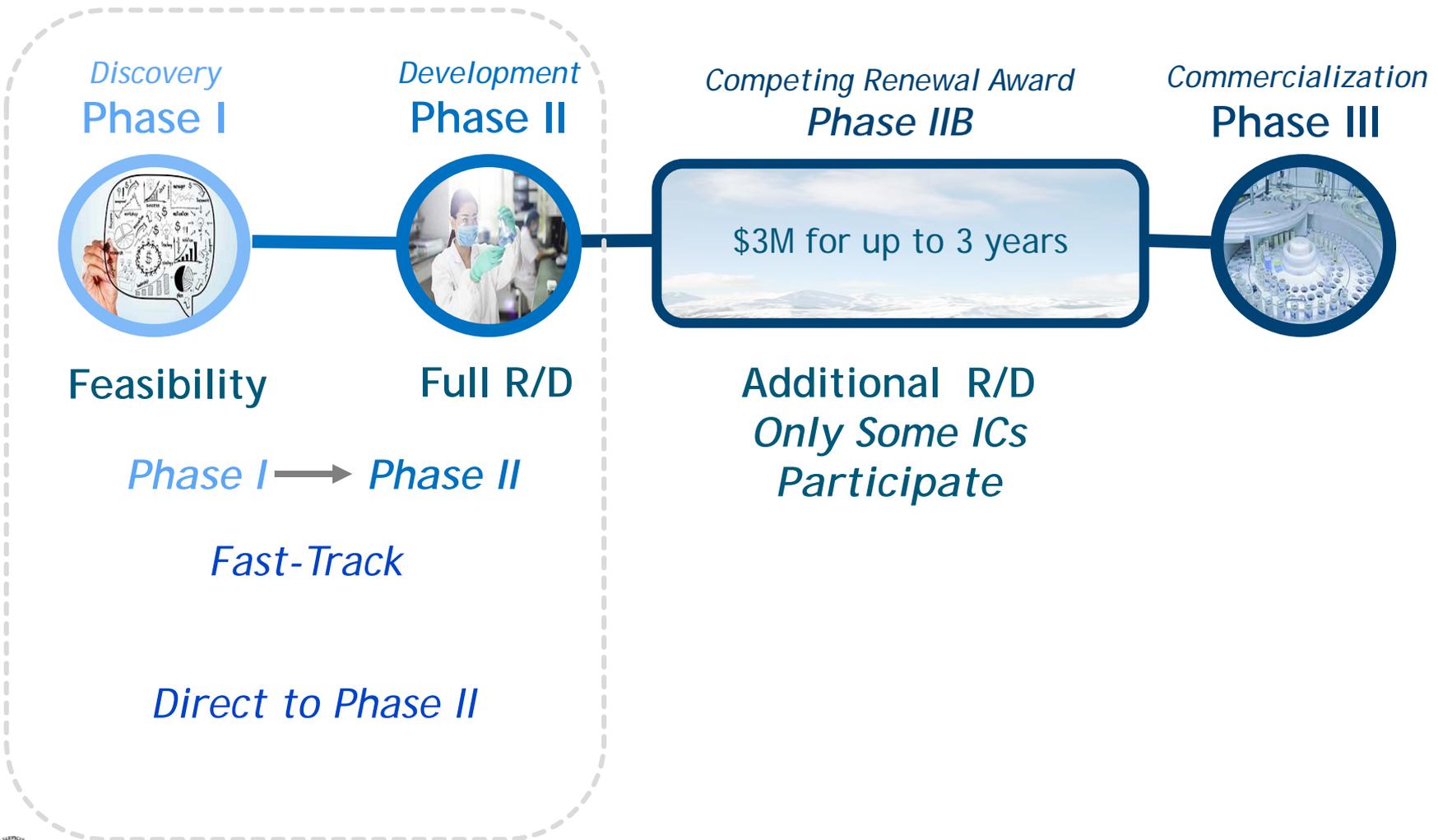
Varies~\$1M per year; up to 3 years

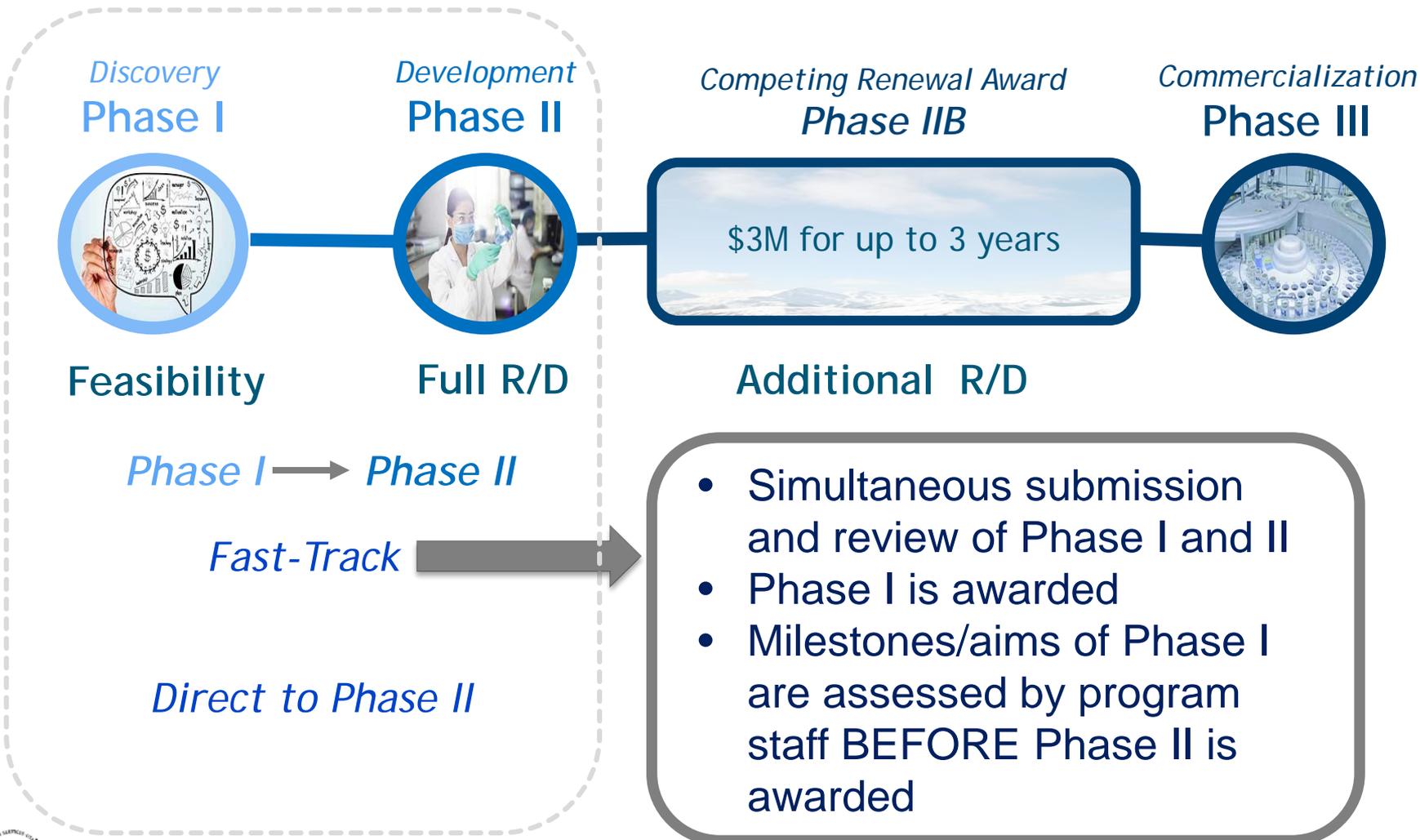
*Commercialization*Phase
III

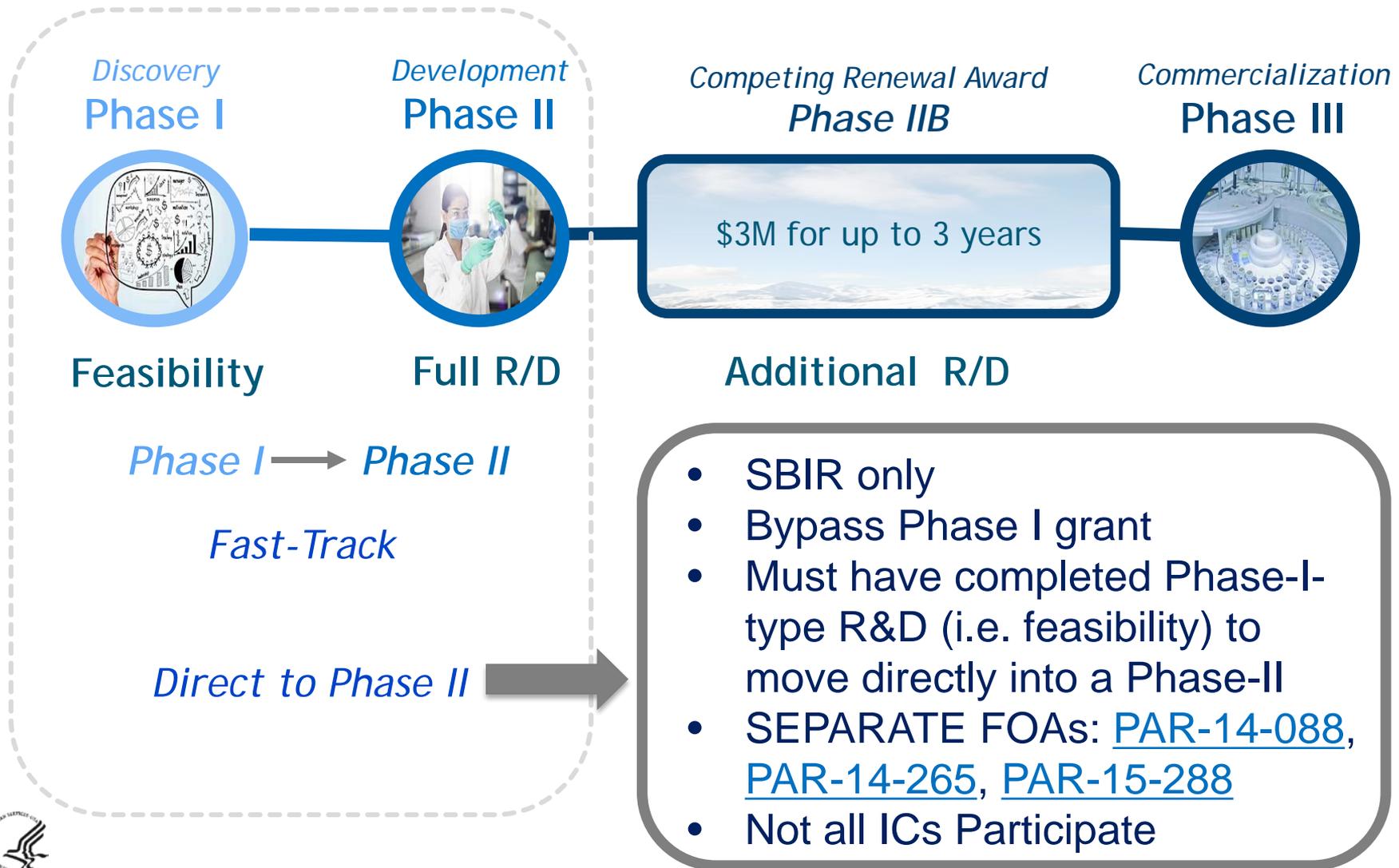
Phase III Commercialization

NIH, generally, not the "customer"

Consider partnering and exit strategy early







<https://sbir.nih.gov>



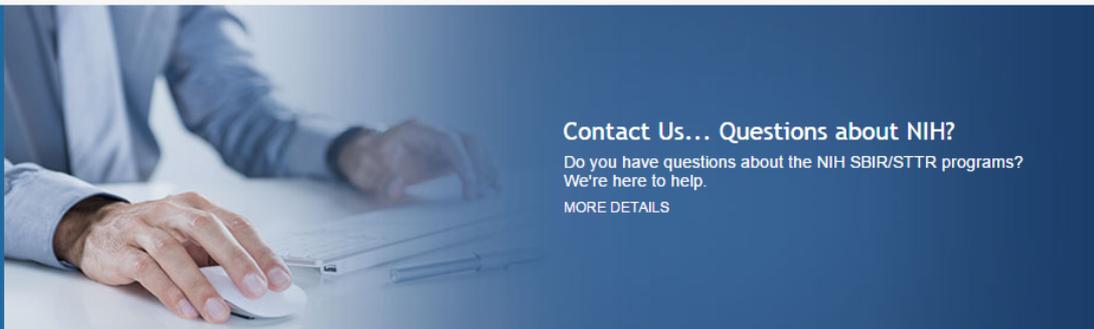
Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SEARCH



SBIR/STTR HOME

- ABOUT
- FUNDING
- APPLY
- REVIEW
- POLICY
- TECHNICAL ASSISTANCE
- RESOURCES
- STATISTICS AND SUCCESSES
- ENGAGE AND CONNECT



Contact Us... Questions about NIH?

Do you have questions about the NIH SBIR/STTR programs? We're here to help.

[MORE DETAILS](#)

New to SBIR/STTR
WHERE TO START



What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are one of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

In Fiscal Year 2015, NIH's SBIR and STTR programs will invest over 780 million dollars into early-stage, health and life science companies that are creating a wide range of innovative technologies that align with NIH's mission to improve health and save lives. A key objective of this work is translating promising technologies to the private sector through strategic public and private partnerships, so that life-saving innovations reach consumer markets.

We invite you to explore our website to learn more about NIH's SBIR & STTR programs, or get started on an application!

HHS SBIR/STTR COMPONENT PROGRAM LINKS

NEWS

- "ASSIST" – a new Option for Small Business Grant Electronic Submission NEW
Sep 24, 2015
- The HHS SBIR Contract Solicitation PHS 2016-1 Has Been Amended
Sep 17, 2015
- CAP Application Deadline Extended until September 18th for Phase II Awardees
Sep 9, 2015



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New to SBIR/STTR
WHERE TO START



NIH SBIR/STTR
REAUTHORIZATION
IMPLEMENTATION



REPORT FRAUD,
WASTE AND ABUSE

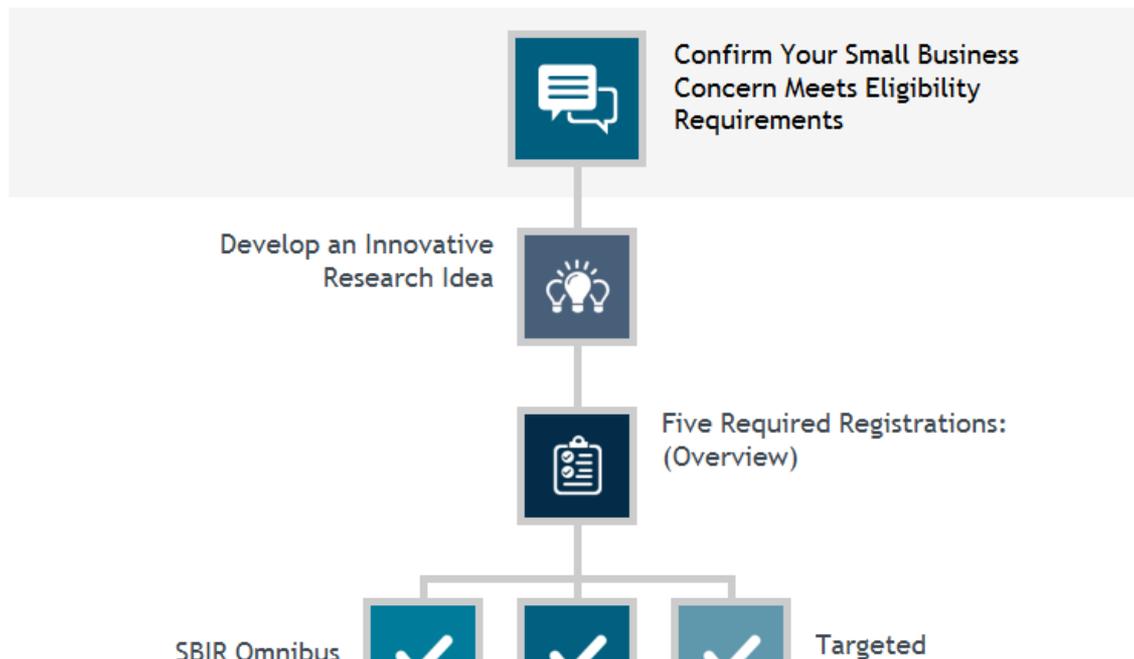


FREQUENTLY ASKED
QUESTIONS

SBIR/STTR Application Process Infographic

Use this interactive chart that contains helpful information to guide you through the NIH SBIR/STTR application process. Click through the chart for answers to your related questions.

**START THE SBIR/STTR
APPLICATION PROCESS
INFOGRAPHIC**





- SBIR/STTR Program Overview
- **Program Eligibility**
- NIH SBIR/STTR Program Specifics
- Solicitations and Funding Opportunities
- The NIH Peer-Review Process
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- Question & Answer





- Organized as for-profit US business
- Small: 500 or fewer employees, including affiliates
- Work must be done in the US (with few exceptions)
- Individual Ownership:
 - Greater than 50% US-owned by individuals and independently operated OR
 - Greater than 50% owned and controlled by other business concern/s that is/are greater than 50% owned and controlled by one or more individuals OR
 - Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these (For FOAs after 1/28/2013 NIH; 7/10/14 CDC)

Determined at Time of Award





SBIR and STTR Critical Differences

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g. university)
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business

Award is always made to the small business





- Eligibility is determined at **time of award**
- PD/PI is not required to have a Ph.D./M.D.
- PD/PI is required to have expertise to oversee project scientifically and technically
- Applications **may be** submitted to **different agencies** for similar work
- Awards may not be accepted from different agencies for duplicative projects





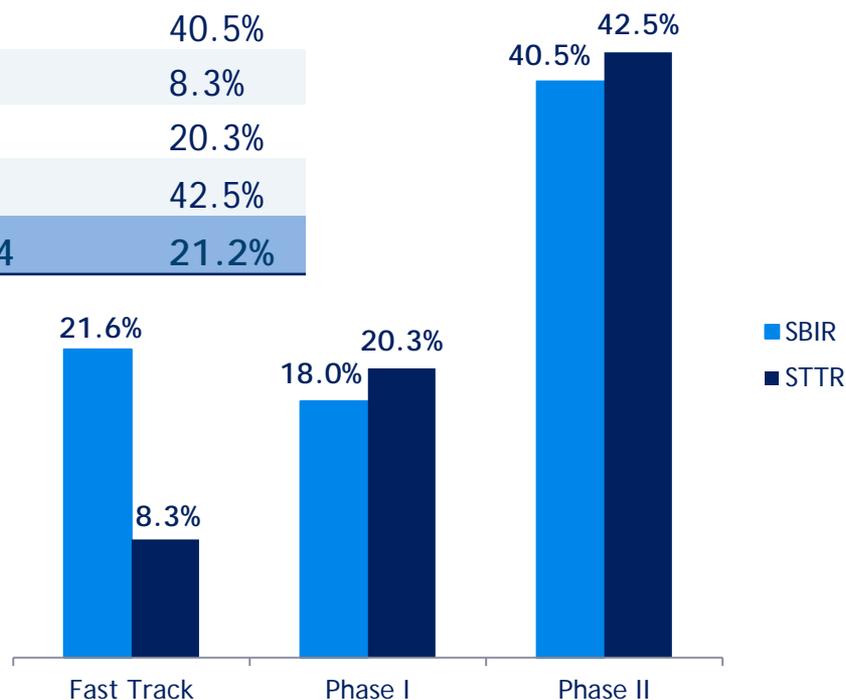
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NIH-wide SBIR/STTR Success Rates FY2014

SBIR/STTR	Phase	# of Applications Reviewed	# of Applications Awarded	Success Rate
SBIR	Fast Track	328	71	21.6%
SBIR	Phase I	3622	652	18.0%
SBIR	Phase II	566	229	40.5%
STTR	Fast Track	60	5	8.3%
STTR	Phase I	788	160	20.3%
STTR	Phase II	87	37	42.5%
FY TOTAL		5,451	1,154	21.2%



Success Rates Posted Online: http://report.nih.gov/success_rates/index.aspx



Be Prepared to Resubmit!



“SBIR is a tough route, and people should be aware of that. The reviewers are not concerned about feelings. But take the criticism seriously, correct the things that need correcting and be prepared to resubmit. Don’t give up because of a depressing review.”



Mary Potasek, Ph.D.

President and Co-founder
Simphotek





- See [NOT-OD-13-071](#) for details
- New SBIR/STTR award budget HARD caps in place

Award Guidelines

Program	Phase I	Phase II
SBIR	\$150,000	\$1,000,000
STTR	\$150,000	\$1,000,000

Award Hard Caps - cannot exceed

Program	Phase I	Phase II
SBIR	\$225,000	\$1,500,000
STTR	\$225,000	\$1,500,000



- Agencies (**not applicants**) must apply for a waiver from the SBA for budgets over the hard cap (\$225,000 for Phase I and \$1,500,000 for Phase II)
- SBA has approved a topics list, which allows budgets to exceed the hard caps as long as the project topics are on the list
- [Pre-approved topics list](#) is Appendix A in [regular topics document](#)
- The approval is good for the 2015 SBIR/STTR Omnibus, and any FOA that falls on the topic list, including the Direct Phase II FOA



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SBIR/STTR HOME

ABOUT

FUNDING

APPLY

REVIEW

POLICY

TECHNICAL ASSISTANCE

RESOURCES

STATISTICS AND SUCCESS

ENGAGE AND CONNECT

NIH SBIR/STTR Funding Opportunity
Announcements

- Funding Opportunity Announcements
- Omnibus SBIR & Omnibus STTR
- Direct Phase II
- Targeted FOAs
- SBIR Phase I Contract
- FAQs

New to SBIR/STTR
WHERE TO START

Each year NIH issues an SBIR and an STTR Omnibus grant solicitation for small businesses, which allow small businesses to submit researcher-initiated projects that are within NIH's mission. The **2015 Program Descriptions and Research Topics** document explains priority research areas for the US Department of Health and Human Service (HHS) SBIR and STTR programs at each of the 24 participating NIH Institutes and Centers (ICs), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA) and the Administration for Children and Families (ACF). You may perform a "Ctrl-F" keyword search to identify NIH ICs that have overlapping program priorities with your research topic, and also use NIH Matchmaker to conduct keyword searches of your topic to identify ICs that have funded research in your area. With any specific idea, you should speak directly with the program official to gauge their interest. Click here to view the Fiscal Year 2015 SBA approved topics for budget waivers.

NIH's Institutes and Centers also issue targeted funding opportunity announcements for certain research areas, as well as an annual NIH SBIR contract. Find out more about the different NIH funding opportunity announcements.

Funding Opportunities for U.S. Small Businesses

If your small business concern (SBC) decides to apply, please use the **SF424 (R&R) SBIR/STTR Application Guide (Version C)**, and the **Annotated SF424 (R&R) SBIR/STTR Form Set (FORMS-C)** for step-by-step instructions on how to complete the application.

Both grant and contract applications require separate forms or appendixes to be attached. Whether an attachment is required or not is often based on how you answer specific questions throughout the application (ie: related to human subject's research). You may find these forms or appendixes in your grant application package that you download from Grants.gov, or you may also access them online, [here](#).

<https://sbir.nih.gov/funding>





- NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation
“Parent” FOAs: [SBIR: PA-15-269](#) [STTR: PA-15-270](#)

Release: June 4, 2015

Standard Due Dates: September 5, January 5, **April 5**

- SBIR Contract Solicitation (NIH, CDC) - SBIR Only

Expected Release: July/August

Expected Close: October/November

- [NIH Guide for Grants and Contracts](#)

Release: Weekly receipt dates specified in each FOA





	Omnibus	Targeted
Due Dates	Standard Due Dates	Standard or Customized Due Dates
Review	SBIR/STTR panels at CSR	SBIR/STTR panels at CSR OR SBIR/STTR panel at IC
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
Participation	All ICs	Varies

Read FOA very carefully!



SBIR/STTR grant applications and SBIR contract proposals must be submitted electronically.

Registrations are required!!!

- DUNS Number (Company)
 - System for Award Management (SAM)
 - Grants.gov (Company)
 - eRA Commons (Company and all PD/PIs)
 - SBA Company Registry at SBIR.gov
- Helpful [NIH Grants Registration Infographic](#)
 - For contracts, submit proposals with [electronic Contract Proposal Submission](#) (eCPS) website



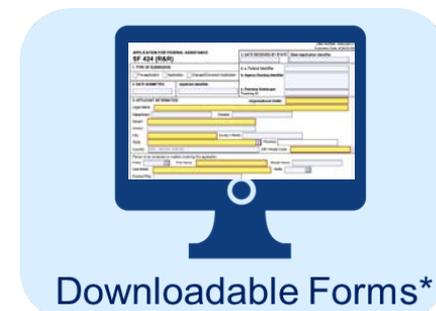
ASSIST

A New Submission Option

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. [Learn more.](#)

Apply Online Using ASSIST

Apply Using Downloadable Forms



* Single-project only



ASSIST is optional, not required!

What is a Women-Owned Small Business (WOSB)?

- A firm must be at least 51% owned and controlled by one or more women, and primarily managed by one or more women (who must be US citizens)
- The firm must be “small” in its primary industry in accordance with SBA’s size standards for that industry
- SBCs self certify on the SF 424 (R&R) Form





What is a Socially and Economically Disadvantaged Business (SDB)?

- The firm must be 51% or more owned and control by one or more disadvantaged persons
- The disadvantaged person or persons must be socially disadvantaged and economically disadvantaged
- The firm must be small, according to SBA's size standards
- You must self-certify by registering your business in the System for Award Management





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Applicant initiates research idea
Program Staff



Small Business Concern confirms Eligibility
Program Staff/SBA



Submits SBIR/STTR grant application to NIH electronically
eRA/Grants.gov Helpdesk



NIH Center for Scientific Review assigns to IC and IRG
Referral Office



IC staff prepare funding plan for IC Director
Program Staff Grants Management



Advisory Council or Board recommend Approval
Program Staff



Scientific Review Group evaluates scientific merit
Scientific Review Officer



IC allocates funds



Grantee conducts research



Applicant initiates research idea



Small Business Concern confirms Eligibility



Submits SBIR/STTR grant application to NIH electronically



NIH Center for Scientific Review assigns to IC and IRG



IC staff prepare funding plan for IC Director



Advisory Council or Board recommend Approval

3 Months



Scientific Review Group evaluates scientific merit

2-4 Months



IC allocates funds



Grantee conducts research



Overall Impact Score

Scored Review Criteria (score 1-9)

- Significance (Real Problem/Commercial Potential)
- Investigators (PI and team)
- Innovation (New or Improved?)
- Approach (Research Design, Feasible)
- Environment (Facilities/Resources)

Additional Review Criteria (not scored individually)

- Protection of Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards





Start-up company, too early for private investment

Seeking funding to produce **feasibility data (Phase 1)**

Seeking funding for **development (Phase 2)**



Aruna Gambhir, MS, MBA

CEO and Co-Founder of CellSight Technologies
NCI SBIR Awardee

“Investors want to see that a technology works. SBIR funding has been critical to our company to show that our technology works.”



Innovative solution to significant unmet clinical need



“My laboratory was working in drug development and it takes a long time to license a technology. It was hard to push forward with only R01 funding and we had neat technology, worth pursuing.”



Lori Hazlehurst, Ph.D.

Professor Pharmaceutical Sciences
West Virginia University

President and Co-founder of
Modulation Therapeutics

- **Talk to an HHS Program Officer** about your application
(at least 1 month before the deadline)
- **SUBMIT EARLY**
 - Program Officer contact information found on the [HHS Agency Contact webpage](#)
 - Questions about who to contact? Email sbir@od.nih.gov





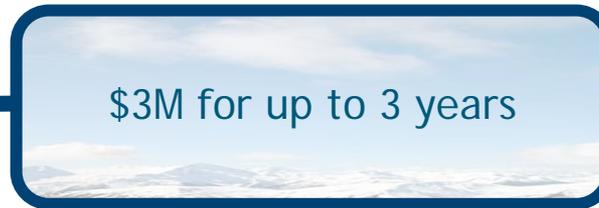
- No Significance
 - Unimportant problem, unconvincing case for commercial potential or societal impact
- Inadequately defined test of feasibility
- Lack of innovation
- Diffuse, superficial, or unfocused research plan
- Questionable reasoning in experimental approach
 - Failure to consider potential pitfalls and alternatives
- Lack of experience with essential methodologies
- Unfamiliar with relevant published work
- Unrealistically large amount of work proposed





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Discovery
Phase IDevelopment
Phase IICompeting Renewal Award
Phase IIBCommercialization
Phase III

- SBIR/STTR Phase II awardee
- Products that require FDA regulatory approval
- Instrumentation/interventional technologies require extraordinary time/effort to develop
- Awards up to **\$1M/year for up to 3 years**
- IC must accept Competing Renewal applications (NIA, NIAAA, NIAID, NICHD, NIDA, NIDCD, NIDDK, NEI, NIGMS NHLBI, NIMH, NINDS, NCATS, ORIP, NCI, NHLBI, NINDS)

Contact NIH Program Staff to discuss!

Commercialization
Readiness Pilot (CRP)Discovery
Phase IDevelopment
Phase IICompeting Renewal Award
Phase IIB

\$3M for up to 3 years

Commercialization
Phase IIICommercialization
Readiness Pilot (CRP)

\$3M for up to 3 years

PAR16-026: Technical Assistance
NINDS/NHLBI/NIA/NIAAA/
NIBIB/NIDDK/NIEHS/NCATS/CDC

PAR16-027: Technical Assistance and
Late Stage Development
NINDS/NEI/NIA/NIAAA/NIAID/
NIAMS/NIDCR/NIDDK/NIMH

Webinar Materials
Available at sbir.nih.gov

Contact NIH Program
Staff to discuss!



Niche Assessment Program Foresight S&T

(Phase I awardees)

- Identifies other uses of technology
- Determines competitive advantages
- Develops market entry strategy



Commercialization Accelerator Program Larta, Inc.

(Phase II awardees)

- “Menu” of technical assistance/training programs in:
 - Strategic/business planning
 - FDA requirements
 - Technology valuation
 - Manufacturing issues
 - Patent and licensing issues
- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting



I-Corps™ at NIH

An intensive *Entrepreneurial Immersion* course for scientists



12 Participating ICs + CDC

Next app date Mar 21st, 2016
PA-16-019

Facilitating Partnerships





Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

IC-Specific Programs

(open to eligible Awardees within Specific ICs)

Workshop on Federal Resources to Accelerate Commercialization (FRAC)

Bringing together NCI SBIR/STTR awardees to move funded technologies from bench to bedside



National Cancer Institute



2009 NCI SBIR INVESTOR FORUM

NOVEMBER 5, 2009
8:00 AM – 6:00 PM

BOSTON UNIVERSITY TRUSTEE BALLROOM
1 Silber Way, 9th Floor
Boston, MA, USA 02115

BOSTON UNIVERSITY



SBIR & STTR

NCI SBIR Investor Forum

November 13, 2014

Agilent Technologies
5301 Stevens Creek Blvd.
Santa Clara, CA 95051



National Heart, Lung, and Blood Institute



November 17, 2015
UCI Applied Innovation
Irvine, CA

NHLBI Innovation Conference





Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

Small Biz Hangouts (Open to the public)



<http://bit.ly/SmallBizHangouts>



National Heart, Lung,
and Blood Institute



Regulatory

- Navigating the FDA Website
- "First Contact" with FDA
- Finding the Right Regulatory Consultant
- Developing a Target Product Profile



Commercialization

- Writing your Phase II Commercialization Plan
- Identifying and Connecting With Your Customer
- How Pharma Evaluates New Therapeutic Opportunities



Intellectual Property

- Intellectual Property Basics for the New Innovator
- Making Your Mark: The Use and Care of Trademarks
- Patent Litigation: Basics, Defense, and Offense – Parts 1 & 2



Get Connected!

- Subscribe to the SBIR/STTR Listserv:
 - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: **subscribe SBIR-STTR your name**
- [NIH Guide for Grants and Contracts](#) (weekly notification)
-  Follow us on Twitter: [@NIHsbir](https://twitter.com/NIHsbir)
- Read our [NIH SBIR/STTR Notable Successes](#)
- [Connect with Us](#)
- Email: sbir@od.nih.gov

