



National Institutes of Health  
Office of Extramural Research



# Investing in Innovation: Understanding the Health and Human Services-NIH Structure for SBIR/STTR Funding

SBA-NCET2 SBIR/STTR Webinar Series 2015

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## Topics to Discuss

### ▶ Where to find information

SBIR/STTR program overview

NIH and CDC SBIR/STTR program specifics

Solicitations and funding opportunities

The NIH peer-review process

Tips for success

Gap-funding programs

Transitioning to the marketplace





U.S. Department of Health & Human Services | National Institutes of Health

OER HOME ABOUT GRANTS FUNDING FORMS & DEADLINES GRANTS POLICY ERA NEWS & EVENTS ABOUT OER

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

Printer Friendly | Text Size A- A+ SEARCH

SBIR/STTR HOME

ABOUT

FUNDING

APPLY

REVIEW

POLICY

TECHNICAL ASSISTANCE

RESOURCES

STATISTICS AND SUCCESSES

ENGAGE AND CONNECT

**New to SBIR/STTR**  
WHERE TO START



CELEBRATING  
**10**  
YEARS

NIH Technical Assistance Programs

- Niche Assessment Program
- Commercialization Assistance Program (CAP)

  
TECHNICAL ASSISTANCE PROGRAMS

  
FUNDING

  
ELECTRONIC SUBMISSION PROCESS

  
SUCCESS STORIES

  
CONTACT US

  
ENGAGE AND CONNECT

## 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 2014, NIH's SBIR and STTR programs will invest over 750 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.

## NEWS

Clarification about the New Standard Due Dates for All HHS SBIR/STTR Grant Applications **NEW**  
*Dec 22, 2014*

Important Change in Standard Due Dates for All HHS SBIR/STTR Grant Applications **NEW**  
*Dec 17, 2014*

Sample SBIR Phase I and Phase II Applications from NIAID Now Available  
*Nov 24, 2014*

<http://sbir.nih.gov>





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

**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**





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

SBIR/STTR HOME  
ABOUT  
FUNDING  
APPLY  
REVIEW  
POLICY  
TECHNICAL ASSISTANCE  
RESOURCES  
STATISTICS AND SUCCESSES  
ENGAGE AND CONNECT

**New to SBIR/STTR**  
WHERE TO START

NIH SBIR/STTR REAUTHORIZATION IMPLEMENTATION

REPORT FRAUD, WASTE AND ABUSE

FREQUENTLY ASKED QUESTIONS

SBIR/STTR Home > NIH SBIR/STTR Reauthorization Implementation

## SBIR/STTR Reauthorization Act Of 2011: NIH Implementation Of Key Changes (What to Expect and When)

The SBIR/STTR Reauthorization Act of 2011 and the recently released SBIR and STTR Policy Directives have brought about numerous changes to the programs many of which are quite complex. NIH is diligently working to implement these changes some of which are easily handled so implemented immediately. Others are more complex and will take time.

The following key change areas have been provided by the Small Business Administration (SBA). Each links to a description of each change and the implementation steps NIH is taking. The information will be regularly updated as NIH progresses so check back regularly. NIH is working with SBA on its implementation plan.

- Funding
- Eligibility
- Stream-lining the Award Process
- Data & Reporting
- Guard Against Fraud, Waste, Abuse
- Support for Commercial-ization

For a full list of changes:

<http://sbir.nih.gov/reauthorization>





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2.9%

## **SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM**

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

0.4%

## **SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM**

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





Set aside requirements for Agencies will increase:

FY	Set-aside SBIR	Set-aside STTR
2013	2.7%	0.35%
2014	2.8%	0.40%
<b>2015 (current)</b>	<b>2.9%</b>	<b>0.40%</b>
2016	3.0%	0.45%
2017	3.2%	0.45%

FY14 NIH SBIR \$663M + NIH STTR \$95M = **\$758M**

**FY15 NIH SBIR \$691M + NIH STTR \$95M = \$786M**





- Stimulate technological innovation
- Use small business to meet federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from federal R&D

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*Small Business Innovation Development Act of 1982*

P.L. 112-81 Re-Authorizes program through FY2017





- Stimulate and foster scientific and technological innovation through **cooperative research** and development carried out *between* **small business concerns** and **research institutions**
- Foster **technology transfer** between small business concerns and research institutions

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*Small Business Research and Development  
Enhancement Act of 1992*

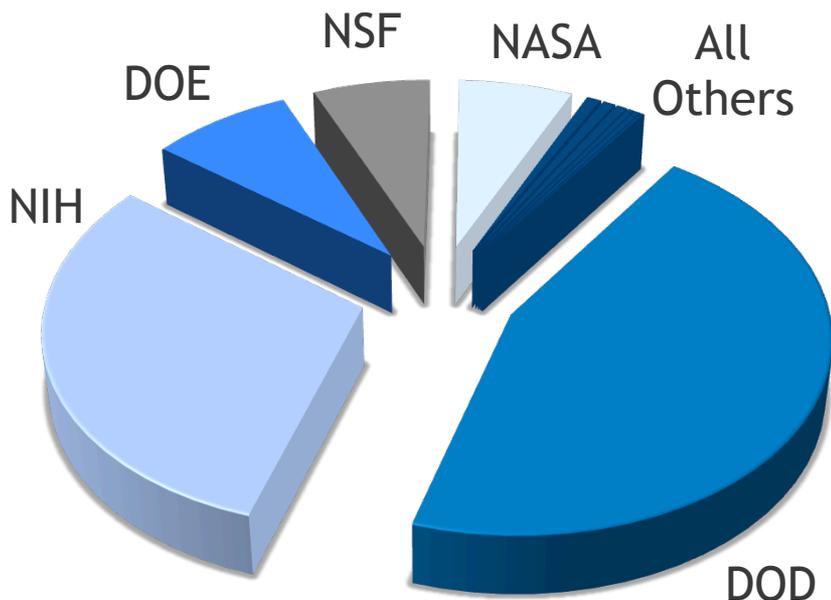
P.L. 112-81 Re-Authorizes program through FY2017



# SBIR/STTR Budgets by Agency FY2013



National Institutes of Health  
Office of Extramural Research



**~ \$2.3B in FY13  
across all agencies**

## Agencies with SBIR and STTR Programs

Department of Defense (DOD)	\$ 1.0 B
Department of Health and Human Services: National Institutes of Health (NIH)	\$697.0 M
Department of Energy (DOE), including ARPA-E	\$183.9M
National Science Foundation (NSF)	\$153.0 M
National Aeronautics and Space Administration (NASA)	\$ 148.8 M

## Agencies with SBIR Programs

U.S. Department of Agriculture (USDA)	\$18.4M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) and Domestic Nuclear Detection Office (DNDO)	\$15.7 M
Department of Education (ED)	\$13.4 M
Department of Transportation (DOT)	\$7.6 M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) and National Institute of Standards and Technology (NIST)	\$7.4 M
Environmental Protection Agency (EPA)	\$3.8 M





## 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/Tools to FDA  
Many, but not all, IC's participate  
Varies~\$1M per year; up to 3 years



## Commercial- ization

Phase III

### Phase III Commercialization Stage

NIH, generally, not the “customer”

Consider partnering and exit strategy early



- Organized as for-profit U.S. business
- Small: 500 or fewer employees, including affiliates
- Work must be done in the U.S. (with few exceptions)
- Individual Ownership:
  - Greater than 50% U.S.- 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**





- Small business concerns that are majority-owned by multiple venture capital operating companies (VCOCs), hedge funds and/or private equity firms ARE NOW ELIGIBLE to apply (**NIH SBIR only, CDC SBIR as of 7/10/14 for new solicitations**)
- See NOT-OD-13-071:  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-071.html>
- SBIR and STTR VCOC forms available at:  
<http://grants.nih.gov/grants/forms.htm#sbir>



*\*Note: SBIR VCOC form also used for SBIR contracts*





- Applicant is a Small Business Concern
- Formal Cooperative R&D Effort
  - Minimum 40% by small business
  - Minimum 30% by US research institution
- US Research Institution
  - College or university; other non-profit research organization; Federal R&D center
- Intellectual Property Agreement
  - Allocation of rights in IP and rights to carry out follow-on R&D and commercialization





# 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 small business**





NIH SBIR/STTR applicants may now ‘switch’ programs at Phase II or Phase IIB to any active NIH SBIR/STTR solicitation.



## Which means:

- Phase I STTR Awardees may apply for NIH SBIR or STTR Phase II
- Phase I SBIR Awardees may apply for NIH SBIR or STTR Phase II
- Phase II STTR Awardees may apply for NIH SBIR or STTR Phase IIB
- Phase II SBIR Awardees may apply for NIH SBIR or STTR Phase IIB

*Note that not all NIH Institutes and Centers accept Phase IIB applications. Check the Omnibus Topics document for listing:*

[http://grants.nih.gov/grants/funding/sbirsttr1/2014-2\\_SBIR-STTR-topics.pdf](http://grants.nih.gov/grants/funding/sbirsttr1/2014-2_SBIR-STTR-topics.pdf)





- 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**





- All SBIR and STTR applicants are required to register with the SBA Company Registry Database
  - <http://www.sbir.gov/registration>
  - Applies to all HHS SBIR/STTR programs, including NIH, CDC, FDA, and ACF
- Attach proof of registration in the Other Project Information, Other Attachments section of the application
  - See section IV.2 of your FOA instructions for details





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2014 Budget	SBIR	STTR
NIH	\$663M	\$95M
CDC	\$8.97 M	N/A
FDA	\$1.29M	N/A
ACF	\$81K	N/A





- CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.
- CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.
- The CDC is one of the major operating components of the Department of Health and Human Services (HHS)
- CDC is comprised of Centers, Institutes, and Offices (CIOs) that allow the agency to be more responsive and effective when dealing with specific public health issues



The CIOs are:

- CDC Washington Office
- Center for Global Health
- National Institute for Occupational Safety and Health (NIOSH)
- Office of Infectious Diseases
  - National Center for Immunization and Respiratory Diseases
  - National Center for Emerging and Zoonotic Infectious Diseases
  - National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
- Office of Noncommunicable Diseases, Injury and Environmental Health
  - National Center on Birth Defects and Developmental Disabilities
  - National Center for Chronic Disease Prevention and Health Promotion
  - National Center for Environmental Health / Agency for Toxic Substances and Disease Registry (ATSDR)
  - National Center for Injury Prevention and Control

## CIOs continued:

- Office of Public Health Preparedness and Response
  - Emergency Operations Center (EOC)
- Office for State, Tribal, Local and Territorial Support
- Office of Public Health Scientific Services
  - National Center for Health Statistics
  - Center for Surveillance, Epidemiology and Laboratory Services
- Office of the Chief of Staff
- Office of the Chief Operating Officer
- Office of Equal Employment Opportunity
- Office of Minority Health and Health Equity
- Office of the Associate Director for Communication
- Office of the Associate Director for Science
- Office of the Associate Director for Policy

- Office of the Associate Director for Science (OADS) manages CDC's SBIR Program and works with CIOs to make determinations as to where the funds would best be used to support high quality, high impact SBIR projects that will be of overall benefit to public health
- CDC participates in the HHS/NIH Omnibus grant and contract solicitations
  - CDC does not participate in STTR Program at this time
  - CDC has opted to participate in the Majority VC ownership authority (FY15)
- Budget - CDC SBIR set-aside approx \$9.0 million

- Topics - Approximately 40 SBIR topics per year plus investigator-initiated research proposals submitted under the grant solicitation which align with CDC research priorities
- Awards -  $\approx$  25 Phase I's up to \$150,000 each and  $\approx$  5-6 Phase II's per year up to \$1.0 M each
- Grants vs. Contracts - 58% grants & 42% contracts in FY 13
- Uniqueness of CDC's SBIR - life sciences; public health; emergency response

- Strengthen surveillance, epidemiology, and laboratory services;
- Improve the ability to support state, tribal, local and territorial public health;
- Improve global health impact;
- Increase policy impact; and,
- Better prevent illness, injury, disability and death.

- To keep pace with emerging public health challenges and to address the leading causes of death and disability, CDC initiated an effort to achieve measurable impact quickly in a few targeted areas
- CDC's Winnable battles are public health priorities with large-scale impact on health and with known, effective strategies to address them

**Tobacco**



**Nutrition,  
Physical Activity,  
Obesity and  
Food Safety**

**Healthcare-  
Associated  
Infections**



**Motor  
Vehicle  
Injuries**

**Teen  
Pregnancy**



**HIV**

## Help CDC as we confront the many public health challenges before us:

- CDC supports groundbreaking health and medical research and real-time emergency response activities to keep America safe, healthy, and secure;
- CDC will promote and fund research and development that supports the mission and/or strategic priorities;
- CDC has roles at the local, state, federal and global levels; and
- The SBIR program is a way for innovators and entrepreneurs to contribute to making the world a healthier and safer place.



# CDC SBIR Contact

**Sean David Griffiths, M.P.H.**

**Email: [SGriffiths@cdc.gov](mailto:SGriffiths@cdc.gov)**

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

Email: [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov)

Web: [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention





*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.***

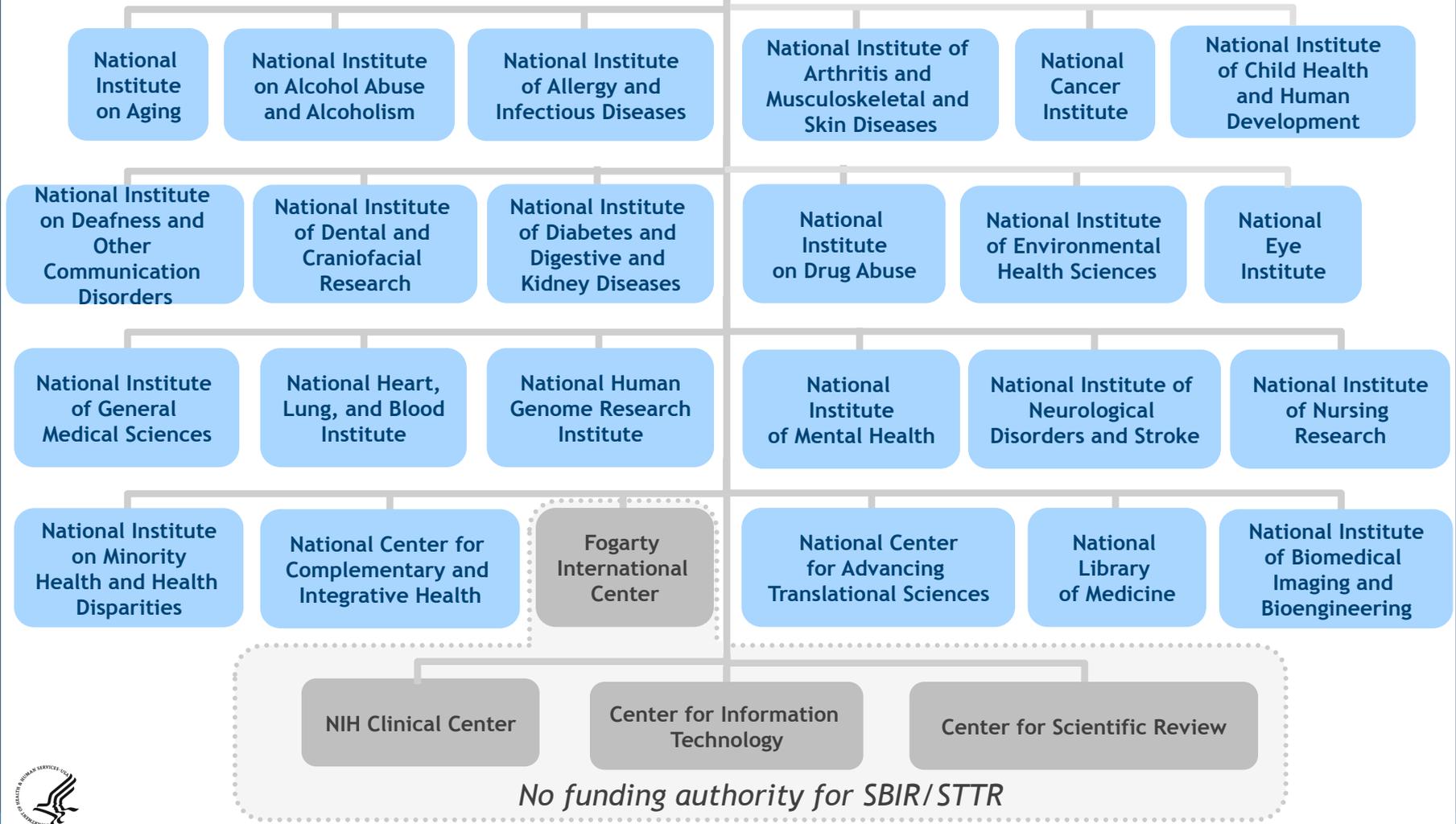




Office of Research  
Infrastructure Programs

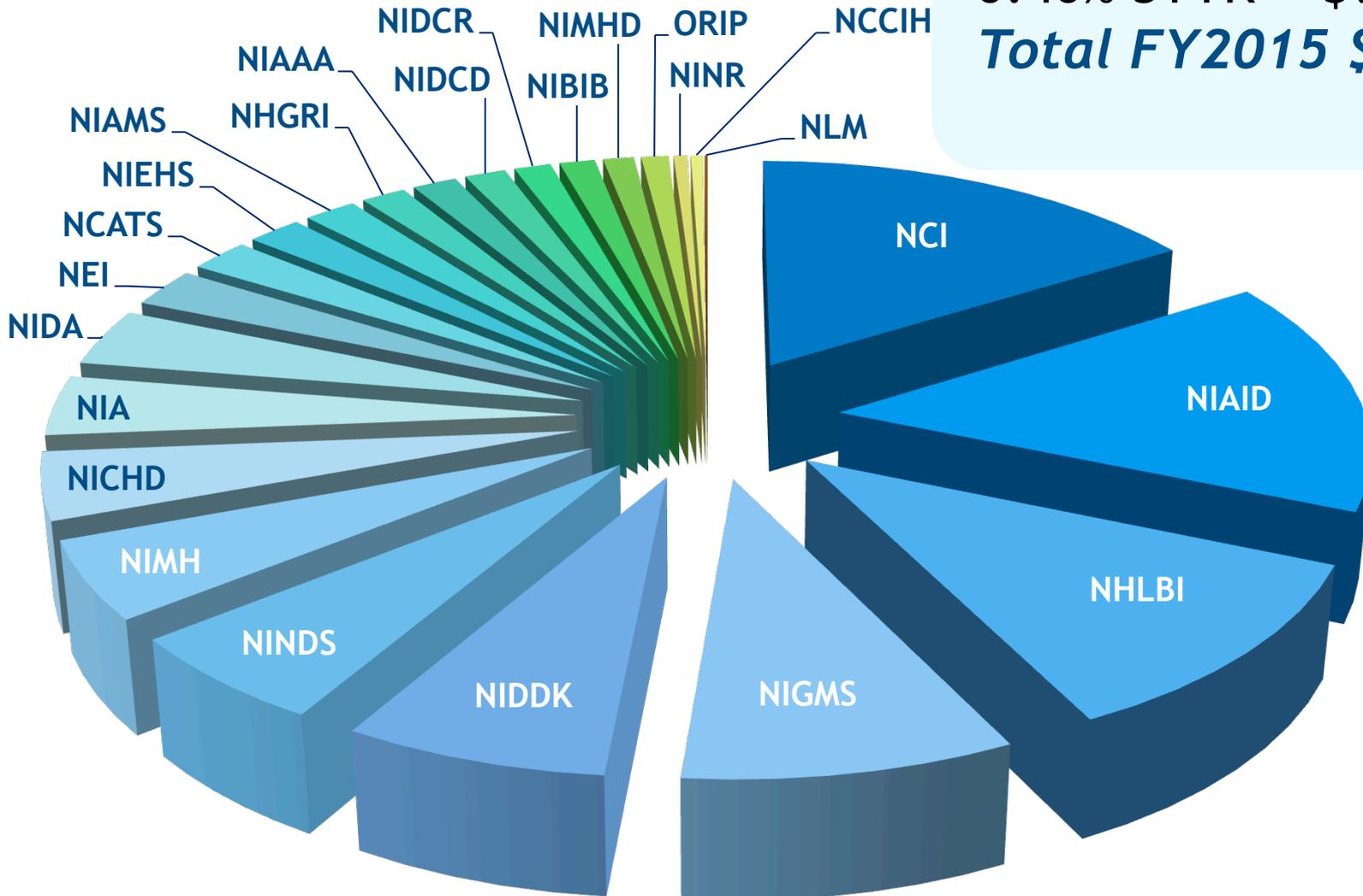
Office of the Director

<http://www.nih.gov/icd>



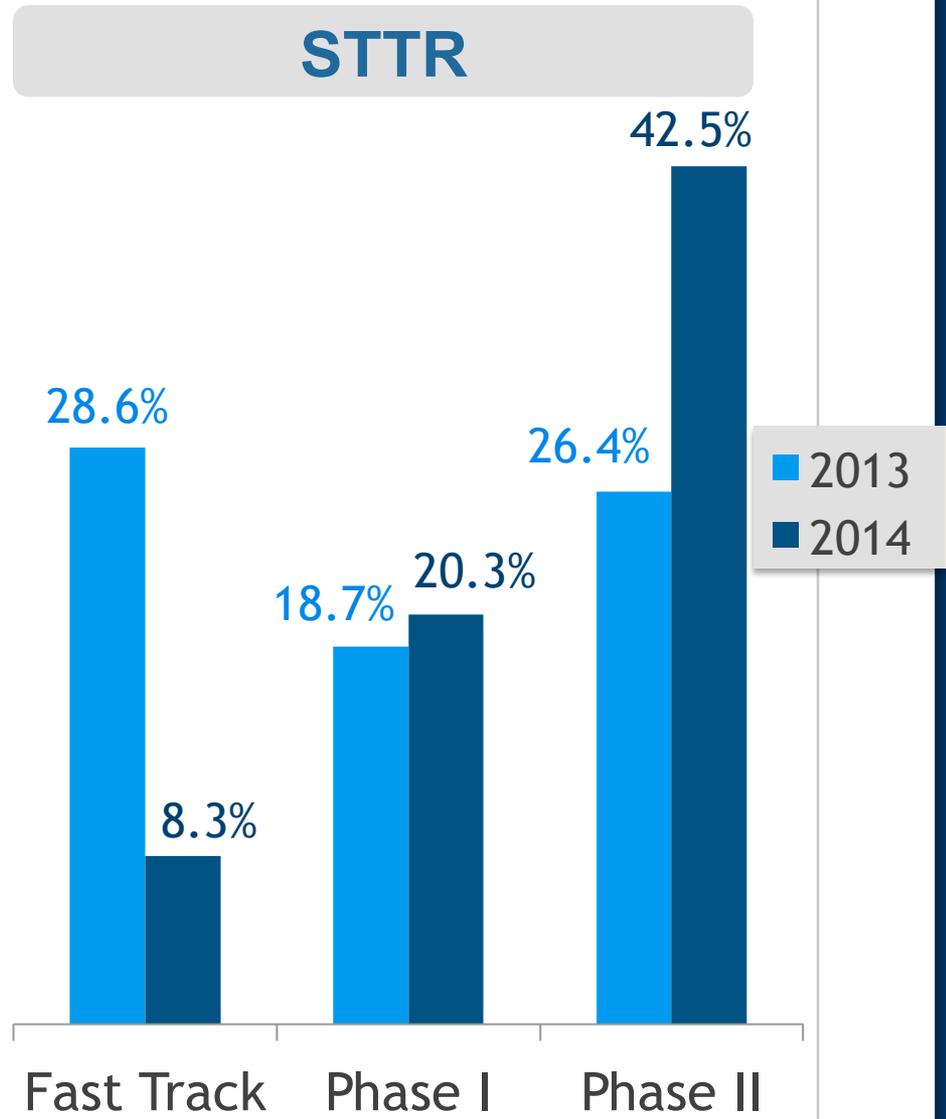
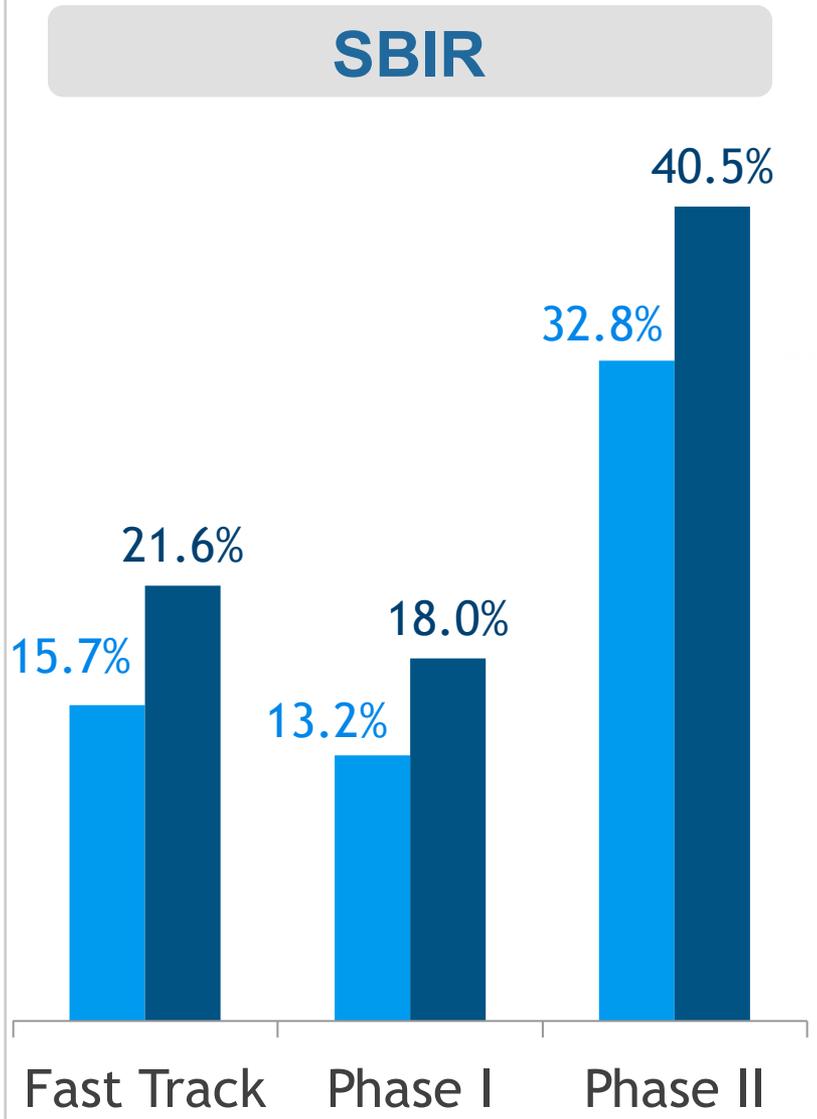
# NIH SBIR/STTR Budget Allocations FY2015

2.9% SBIR     \$691M  
0.40% STTR     \$95M  
**Total FY2015 \$786M**





# Success Rate of SBIR/STTR 2013 and 2014 by Phase



■ 2013  
■ 2014



# NIH-wide SBIR/STTR Success Rates 2013-2014

Fiscal Year	<u>SBIR<sup>1</sup>/STTR<sup>2</sup></u>	<u>Phase<sup>3</sup></u>	Number of Applications Reviewed	Number of Applications Awarded	<u>Success Rate<sup>4</sup></u>	<u>Total Funding<sup>5</sup></u>
2013	SBIR	Fast 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	Fast 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
<b>2013</b>	<b>FY TOTAL</b>		<b>5,290</b>	<b>862</b>	<b>16.3%</b>	<b>\$302,036,519</b>
2014	SBIR	Fast 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	Fast 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
<b>2014</b>	<b>FY TOTAL</b>		<b>5,451</b>	<b>1,154</b>	<b>21.2%</b>	<b>\$391,328,419</b>



Success Rates Posted Online: [http://report.nih.gov/success\\_rates/index.aspx](http://report.nih.gov/success_rates/index.aspx)



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

SEARCH

**SBIR/STTR HOME**

- ABOUT
- FUNDING
  - NIH SBIR/STTR Funding Opportunity Announcements
    - Funding Opportunity Announcements
    - Omnibus SBIR & Omnibus STTR
    - Direct Phase II
    - Targeted FOAs
    - SBIR Phase I Contract
    - FAQs
- APPLY
- REVIEW
- POLICY
- TECHNICAL ASSISTANCE
- RESOURCES
- STATISTICS AND SUCCESS
- ENGAGE AND CONNECT

**New to SBIR/STTR**  
WHERE TO START

- NIH SBIR/STTR REAUTHORIZATION IMPLEMENTATION
- REPORT FRAUD, WASTE AND ABUSE
- FREQUENTLY ASKED QUESTIONS

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 2014 **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 do a "Ctrl-F" keyword search to identify NIH Institutes and Centers that have overlapping program priorities with your research topic. With any specific idea, you should speak directly with the program official to gauge their interest.

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](#).

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





- NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation  
“Parent” FOAs: **SBIR: [PA-14-071](#)**      **STTR: [PA-14-072](#)**

Release: ~~January~~ June

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

***No August 5, 2015 Due Dates (See [NOT-OD-15-038](#))***

***No separate AIDS dates for Standard Due Dates***

- SBIR Contract Solicitation (NIH, CDC)

Release: August

Close Date: November

- NIH Guide for Grants and Contracts

Release: Weekly Receipt dates specified in each FOA

**<http://grants.nih.gov/grants/guide/index.html>**





- PA-14-071 and PA-14-072 extended by one cycle to allow April 5, 2015 and expires on 5/8/2015.
- See Notices [NOT-OD-15-036](#) and [NOT-OD-15-037](#).
- Adjust timing of next and future Omnibus issuances





- 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: <http://1.usa.gov/1iUa5Kh>
- The approval is good for the 2014 SBIR/STTR Omnibus, and any FOA that falls on the topic list, including the Direct Phase II FOA





## Our Ideas: Suggested topic areas\*

- Biodefense
- Biosensors
- Nanotechnologies
- Bioinformatics
- Diagnostic and Therapeutic **Devices**
- Telehealth
- Proteomics / Genomics
- Biosilicon devices
- Biocompatible **materials**
- Acousto-optics / opto-electronics
- Health IT
- **Imaging** devices
- Genetically engineered proteins
- ...





## YOUR Ideas: Investigator-initiated R&D

- Research projects related to the NIH mission
- “Other” areas of research within the mission of an awarding component

**Keyword Search the Solicitation**  
**Ctrl + F**





## NIH Guide for Grants and Contracts

- High priority areas for ICs
- Various IC participation
- Nuances:
  - Various due dates
  - Additional review criteria
  - Limited funds
  - Varying project periods
  - Etc.

<http://sbir.nih.gov/funding#targeted>



SBIR/STTR grant applications must be submitted electronically. SBIR contract proposals still in paper form.

## 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



<http://era.nih.gov/applicants/index.cfm>

## What is a Women-Owned Small Business?

- 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
- <http://1.usa.gov/1d10b5q>



## 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](#)
- <http://1.usa.gov/1mKnU0a>



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# NIH Application and Review Process



Applicant Initiates  
Research Idea



Small Business  
Concern



Submits SBIR/STTR  
Grant Application to  
NIH Electronically



NIH Center for  
Scientific Review/  
Assign to IC and IRG



IC Staff Prepare  
funding Plan For  
IC Director



Advisory Council or  
Board Recommend  
approval



Scientific Review  
Groups Evaluate  
Scientific Merit



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





# Timeline: New Applications



Due Date	Scientific Review	Council Review	Award Date (earliest)
Sept 5	Oct/Nov	Jan/Feb	March
Jan 5	Feb/Mar	May/June	July
April 5	June/July	Aug	Sept or Dec





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Gap-funding programs

Transitioning to the marketplace





- 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





- Understand our mission
- Review Funding Opportunity Announcements (FOAs)
- Propose innovative ideas with significance as well as scientific and technical merit
- Give yourself ample time to prepare application
- **Communication, Communication, Communication**
- Contact NIH Staff to discuss
  - your research idea
  - outcome of your review
  - challenges and opportunities





- Talk to an NIH Program Officer about your application and **SUBMIT EARLY** (days not hours and minutes)!
  - Program Officer contact information found in the NIH SBIR/STTR Solicitation on <http://sbir.nih.gov>
  - Questions about who to contact? Email [sbir@od.nih.gov](mailto:sbir@od.nih.gov)





## Topics to Discuss

Where to find information

SBIR/STTR program overview

NIH and CDC SBIR/STTR program specifics

Solicitations and funding opportunities

The NIH peer-review process

Tips for success

### ▶ **Gap-funding programs**

Transitioning to the marketplace





Phase I

## SBIR/STTR Phase I/ Phase II Fast Track

Phase II

*(Simultaneous Submission And  
Concurrent Review)*

*Peer  
Review &  
Decisions*



### Phase I Award

Phase I

## Completion of Phase I

*Phase I  
Final  
Report*



Program Staff  
Assess completion of  
specific aims and  
milestones



Phase II  
Awarded



Phase II  
NOT Awarded





## Important Considerations

- Convincing preliminary data
- Clear, measurable, achievable milestones
- Well-conceived Commercialization Plan
- Letters of Phase III support/interest?
- Track record for commercializing?
- Discussed with NIH Program Staff?





- Allows small businesses that are ready for the Phase II stage of development to bypass applying for a Phase I grant.
- The SBC must already have a technology prototype, and must have tested its feasibility (i.e. completed Phase-I-type R&D) to move directly into a Phase-II-type R&D.
- SBIR Direct to Phase II Solicitations have their own SEPARATE FOAs: [PAR-14-088](#), [PAR-14-265](#)

NIH SBIR Direct to Phase II Pilot Solicitation/s

PAR-14-088  
PAR-14-265 (NINDS only)

Standard Receipt Dates:

- September 5
- January 5
- April 5

AIDS and AIDS-Related Receipt Dates:  
\*Good through May 7, 2015

- May 7
- September 7
- January 7

<http://sbir.nih.gov/funding#phase2>



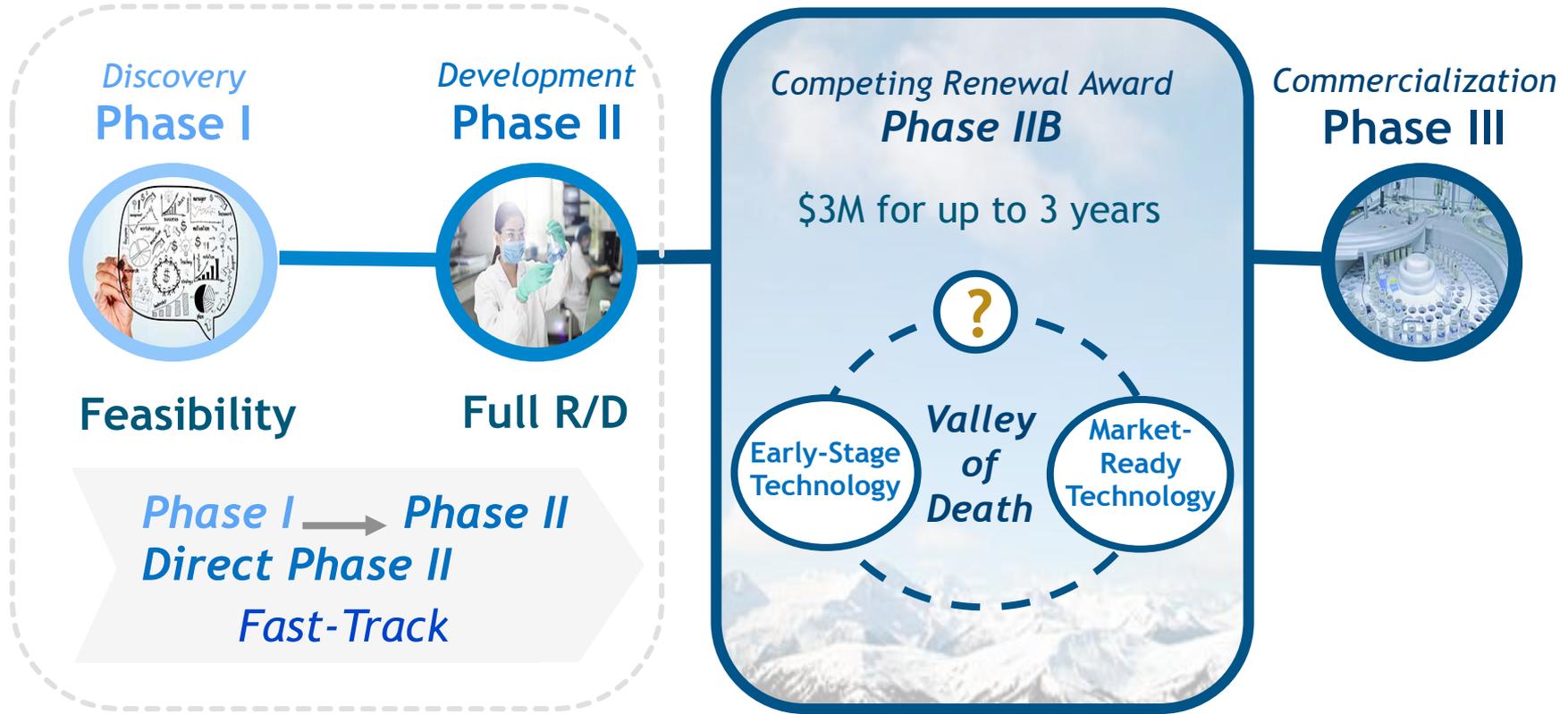


- Not all ICs will accept Direct Phase IIs - only the ones listed on the solicitation(s). SBCs cannot apply for a Phase II and Direct Phase II for the same research project.
- All ICs on the Direct Phase II will accept technology on anything within their mission. Note: NINDS has a few exceptions listed within the FOA.
- Applicants are strongly advised to talk to their SBIR Program Officer before applying.
- No due dates past 1/5/2017 standard date.
- The Direct-to-Phase II authority is not available to the STTR program and not available for the CDC, FDA, and ACF SBIR programs.





# NIH SBIR/STTR: 3-Phase Program Plus Gap Funding





## Parameters

- SBIR/STTR Phase II awardee
- Promising pharmacologic compound identified in original Phase II
- Device prototype developed in original Phase II
- Instrumentation/Interventional technologies not subject to FDA regulatory approval but 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!**





## Topics to Discuss

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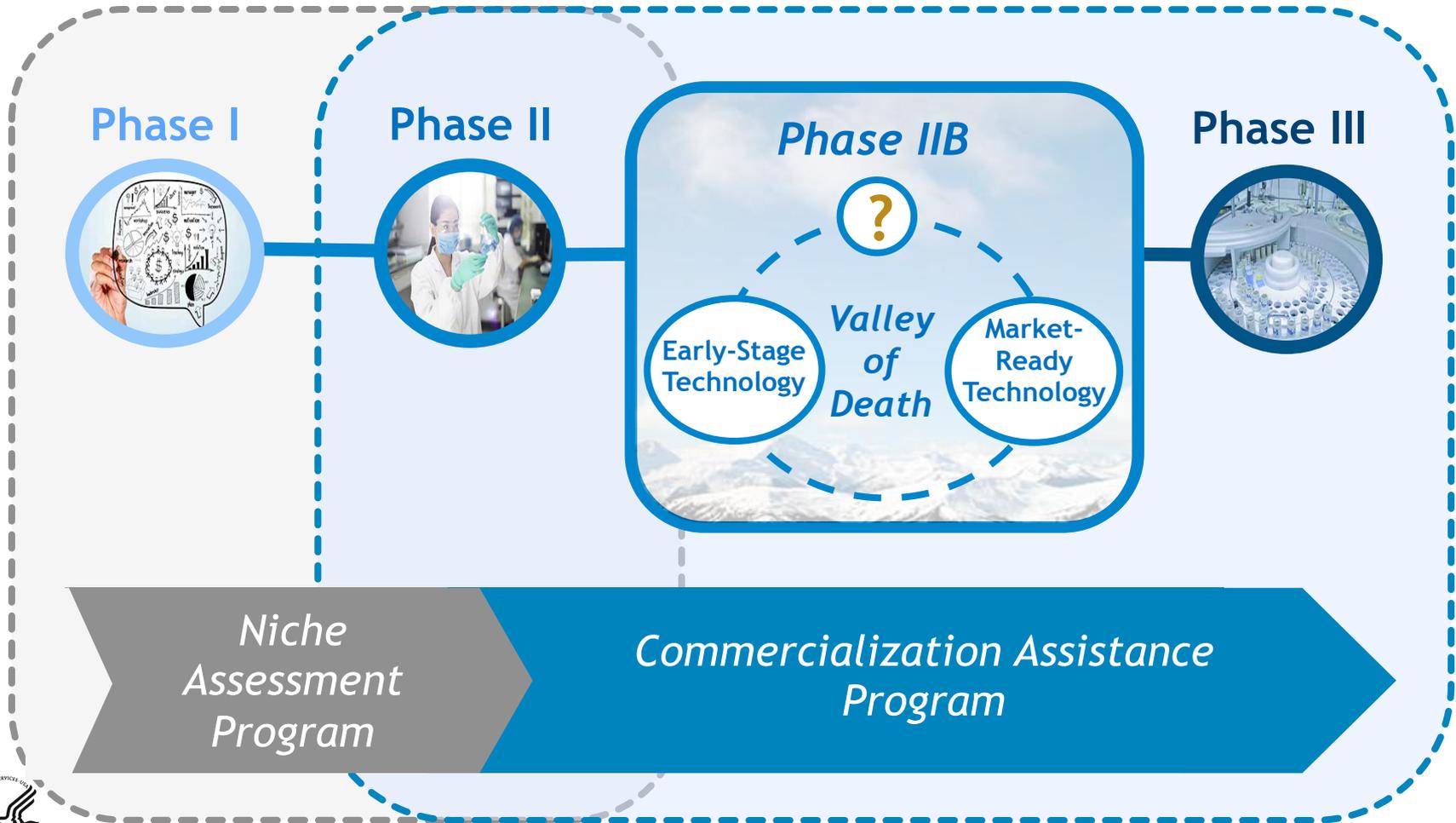
Gap-funding programs

▶ **Transitioning on the marketplace**





## Helping Companies cross the “Valley of Death”





## Niche Assessment Program Foresight S&T

(Phase I awardees)

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



## Commercialization Assistance 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





## Technical Assistance Options

- NIH offers distinct [technical assistance programs](#) to SBIR Phase I and Phase II awardees (Niche & CAP)
- Applicants wishing to utilize their own technical assistance vendor are required to include this in your budget and provide a detailed budget justification
- Please note, if funds are requested to utilize your own technical assistance vendor and an award is made, the awardee is not eligible to apply for the NIH-provided technical assistance program for the phase of their award





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## Get Connected!

- Subscribe to the SBIR/STTR Listserv:
  - Email [LISTSERV@LIST.NIH.GOV](mailto: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)  
<http://grants.nih.gov/grants/guide/listserv.htm>
-  Follow us on Twitter: @NIHsbir
- Submit your SBIR/STTR Success Story at: <http://sbir.nih.gov>
- Email: [sbir@od.nih.gov](mailto:sbir@od.nih.gov)





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- NINDS Website: [ninds.nih.gov/otr](https://ninds.nih.gov/otr)

