National Institutes of Health
Office of Extramural Research

Exploring the NIH SBIR/STTR Funding Programs

February 3, 2017

Nebraska Business Development Center

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SBIR/STTR Program Manager

Office of Extramural Research, NIH

Agenda

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

Most Important Piece of Advice

- Talk to an HHS Program Officer about your application and **SUBMIT EARLY** **(days not hours and minutes)!**
  - Program Officer contact information found on the HHS Agency Contact webpage
  - Questions about who to contact? Email sbir@od.nih.gov

NIH SBIR/STTR Website

https://sbir.nih.gov

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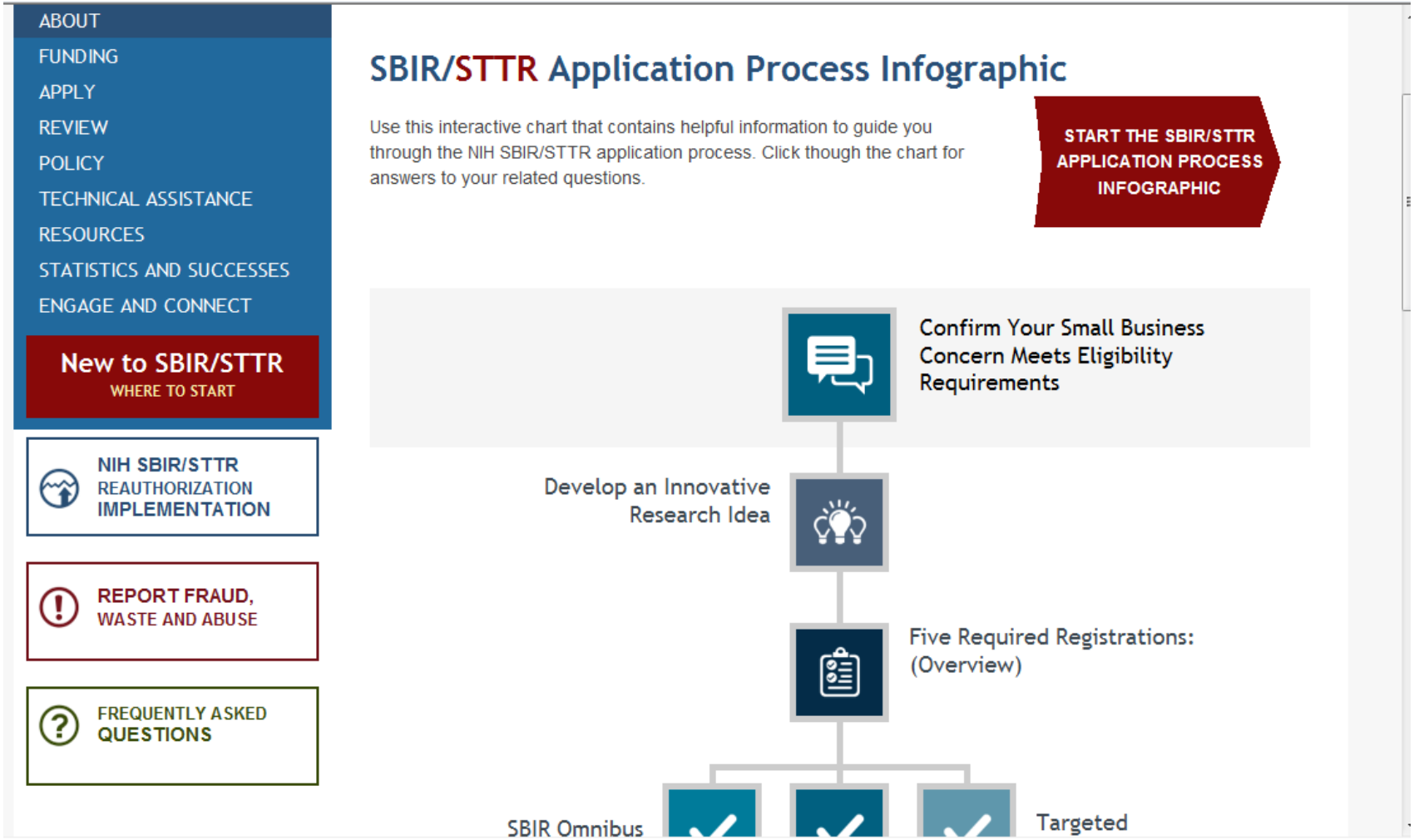
http://sbir.nih.gov/infographic



Congressionally Mandated Programs

SET ASIDE

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

3.0% (FY16)

3.2% (FY17)

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

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

.45% (FY16)

.45% (FY17)

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

SBIR Purpose and Goals

- 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

Small Business Innovation Development Act of 1982

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

STTR Purpose and Goals

- 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

Small Business Research and Development Enhancement Act of 1992

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

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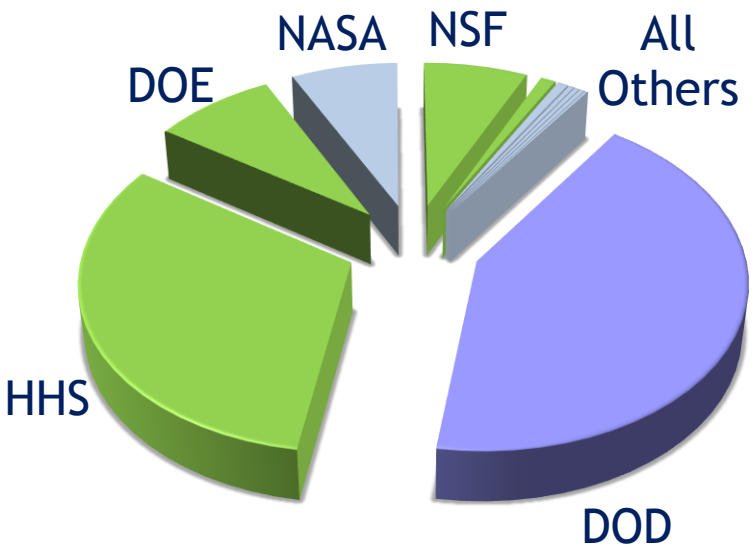
SBIR/STTR Budgets by Agency FY2015



~ $2.5B in FY15 across all agencies

Grants

Contracts

SBIR · STTR
America's Seed Fund

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

HHS Program Funding

2016 Budget	SBIR	STTR
NIH	$763M	$114M
CDC	$9M	N/A
ACL (NIDILRR)	$2.7M	N/A
FDA	$1.55M	N/A
ACF	$93.5K	N/A

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NIH SBIR/STTR 3-Phase Program

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

SBIR Eligibility Criteria

- 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

STTR Eligibility Criteria

- 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 the small business

Important Facts to Remember

- 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 Mission

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.***

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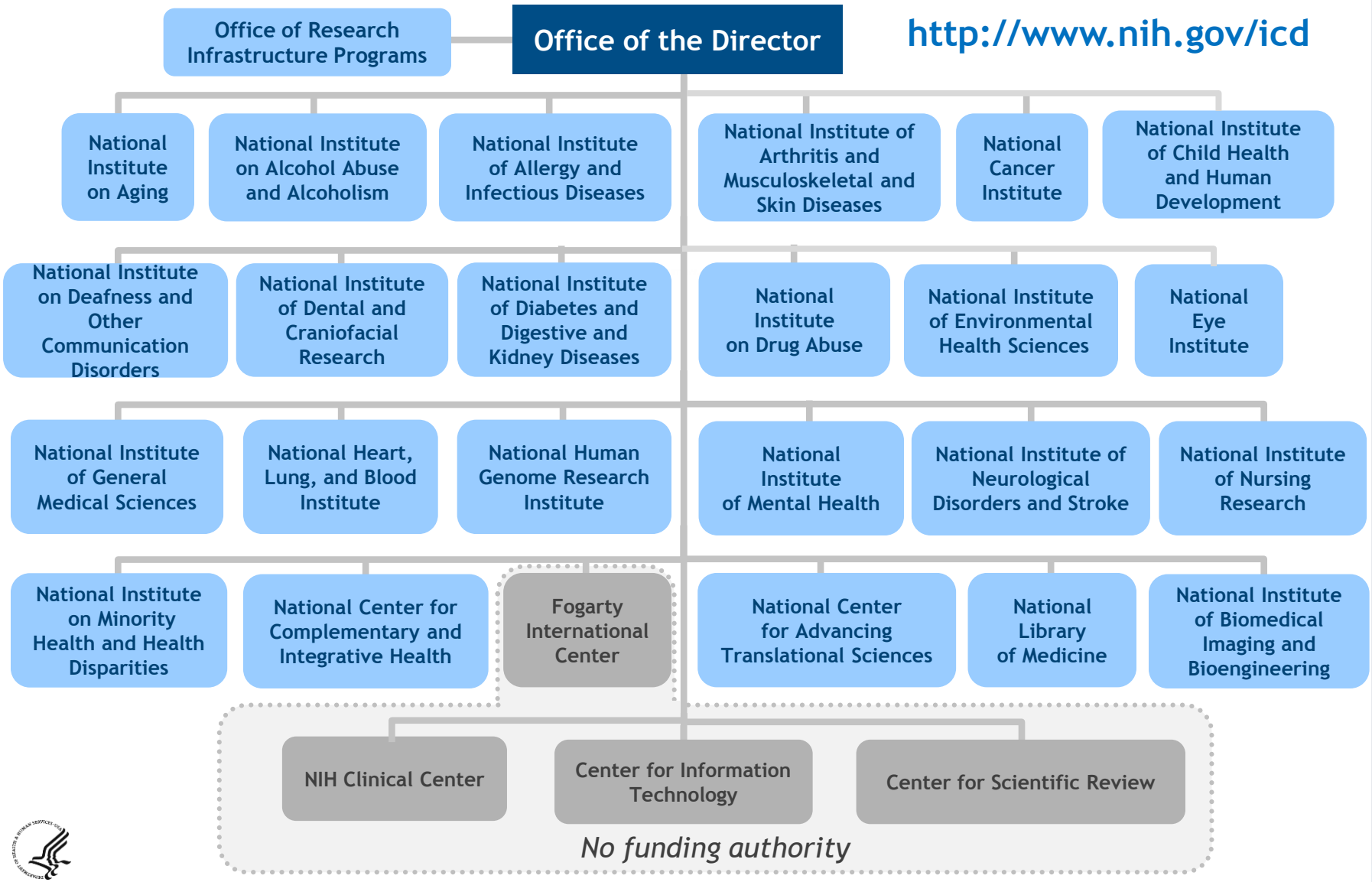

NIH SBIR/STTR Budget Allocations FY2016

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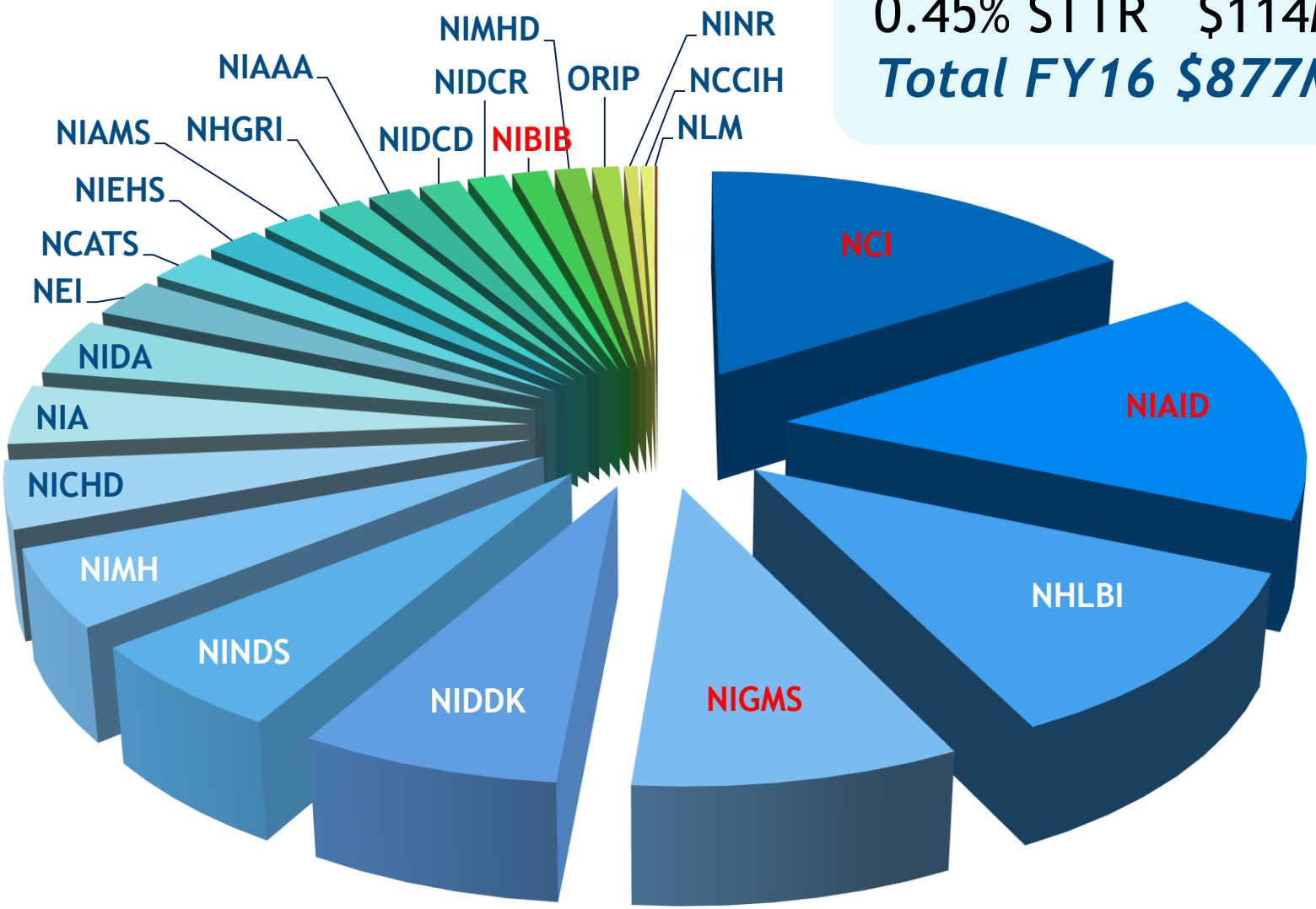
3.0% SBIR $763M
0.45% STTR $114M
Total FY16 $877M



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NIH SBIR/STTR 3-Phase Program

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Additional R/D
Only Some ICs Participate

Commercialization
Phase III

Phase I → *Phase II*

Fast-Track

Direct to Phase II

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NIH SBIR/STTR Fast-Track

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Additional R/D

Commercialization
Phase III

Phase I → ***Phase II***

Fast-Track

Direct to Phase II

- Simultaneous submission and review of Phase I and II
- Phase I is awarded
- Milestones/aims of Phase I are assessed by program staff BEFORE Phase II is awarded

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NIH SBIR/STTR
Direct to Phase II

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Additional R/D

Commercialization
Phase III

Phase I → ***Phase II***

Fast-Track

Direct to Phase II →

- SBIR only
- Bypass Phase I grant
- Must have completed Phase-I-type R&D (i.e. feasibility) to move directly into a Phase-II
- SEPARATE FOAs: https://sbir.nih.gov/funding#phase2
- Not all ICs Participate

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Phase IIB Competing Renewal Award

- SBIR/STTR Phase II awardee
- Technologies that require extraordinary time/effort to develop, and often require FDA regulatory approval
- 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!

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Commercialization Readiness Pilot (CRP)

Discovery
Phase I

Development
Phase II

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Commercialization
Phase III

Commercialization Readiness Pilot (CRP)

$3M for up to 3 years

PAR16-026: Technical Assistance
PAR16-027: Technical Assistance and Late Stage Development

Webinar materials available at sbir.nih.gov

Contact NIH Program Staff to discuss!

Commercialization Readiness Pilot Program (CRP) – NEW!

- CRP may fund work that is **not** typically supported through SBIR/STTR Phase II or Phase IIB awards, including:
  - Preparation of documents for a Food and Drug Administration (FDA) submission
  - Development of an intellectual property strategy
  - Investigational New Drug (IND)-enabling studies
  - Clinical studies
  - Manufacturing costs
  - Regulatory assistance
  - Subcontracted work to other institutions, including contract research organizations (CRO)
  - A combination of services

- HHS CRP Informational Webinar (December 2, 2015)
  - Webinar, slides, transcript @ http://grants.nih.gov/CRP%20Webinar

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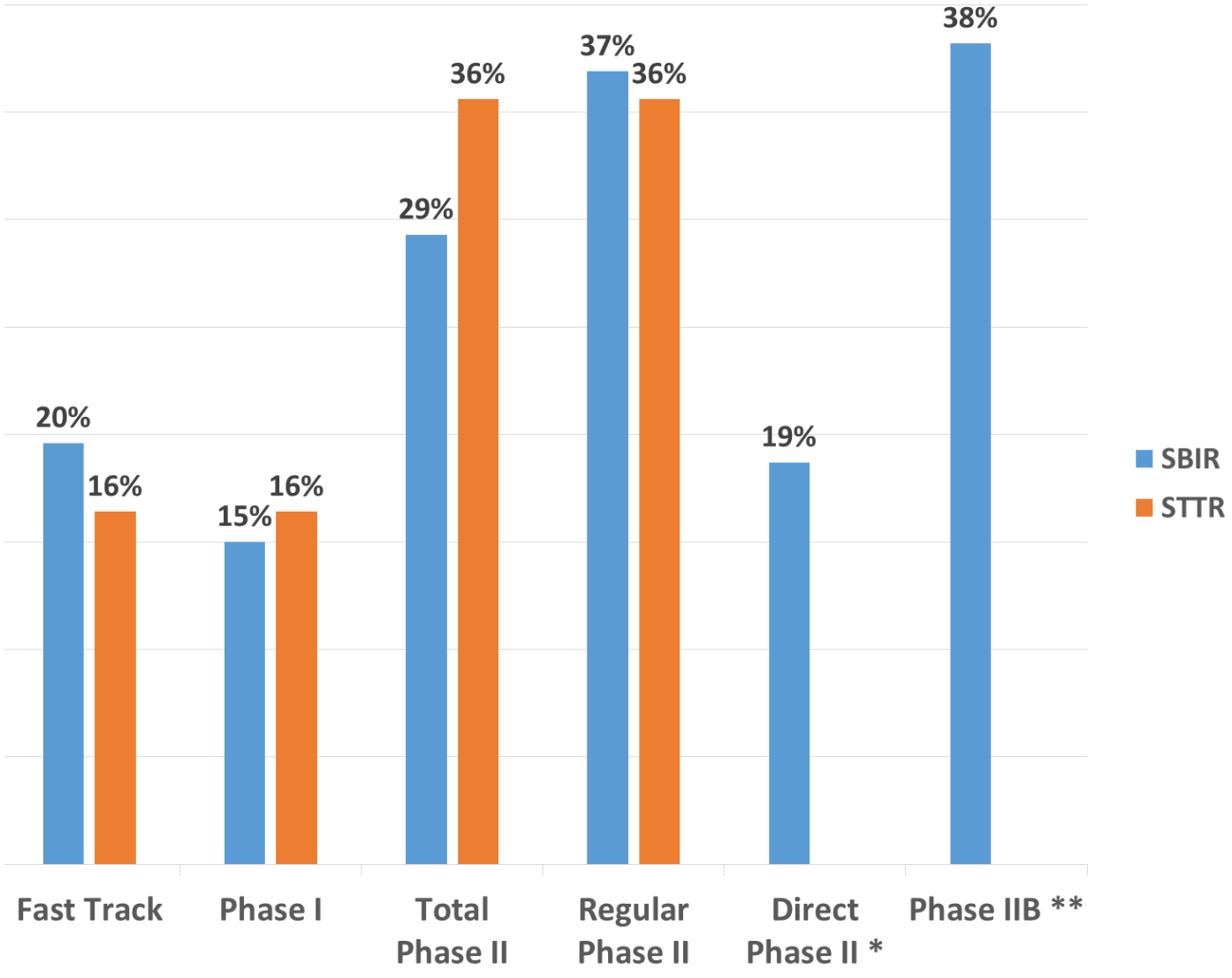
Grant Success Rate of SBIR/STTR 2015 by Phase



**STTR does not offer Direct Phase II*

***In FY15, there were no Phase IIB STTRs*

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NIH-wide SBIR/STTR Grant Success Rates 2015

Fiscal Year	SBIR/STTR	Phase	No. Applications Reviewed	Number Applications Awarded	Success 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**	**Total Phase II**	**823**	**241**	**29.3%**	**$179,946,727**
2015	SBIR	Regular Phase II	442	163	36.9%	$113,088,150
2015	SBIR	Direct Phase II	347	65	18.7%	$55,150,363
2015	SBIR	Phase IIB	34	13	38.2%	$11,708,214
2015	STTR	Fast Track	61	10	16.4%	$2,171,909
2015	STTR	Phase I	911	149	16.4%	$33,782,224
2015	**STTR**	**Total Phase II**	**87**	**31**	**35.6%**	**$21,597,183**
2015	STTR	Regular Phase II	87	31	35.6%	• $21,597,183
2015	**FY TOTAL**		**5,644**	**1,011**	**17.9%**	**$372,766,143**

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

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Budget Hard Caps

- 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

Budget Hard Cap Waiver

- 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 2016 SBIR/STTR Omnibus, and any FOA that falls on the topic list, including the Direct Phase II FOAs

Venture Capital Companies

- 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 to **NIH and CDC SBIR**
- See NOT-OD-13-071
- SBIR and STTR VCOC forms available online

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

Switching between SBIR and STTR

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.

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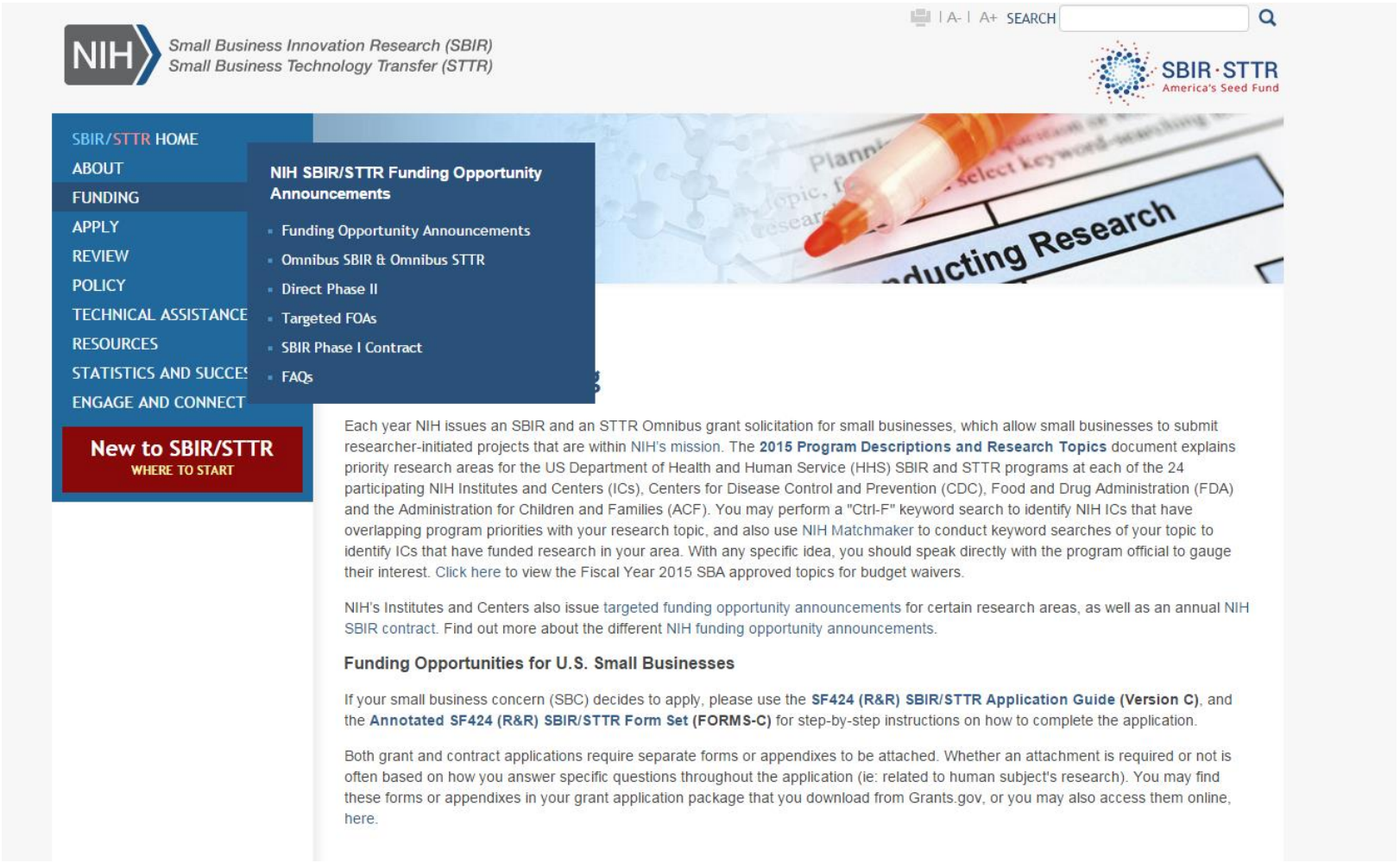
NIH SBIR/STTR FOAs



https://sbir.nih.gov/funding

Solicitations and Due Dates

- **NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation "Parent" FOAs: SBIR: PA-16-302 STTR: PA-16-303**

  Release: June 3, 2016

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

- **SBIR Contract Solicitation (NIH, CDC) - Program Solicitation PHS 2017-1 (SBIRs Only)**

  NIH Guide Notice NOT-OD-16-123

  Release: August 1, 2016 Close: October 21, 2016 (5pm EDT)

- **NIH Guide for Grants and Contracts**

  Release: Weekly receipt dates specified in each 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

Omnibus vs Targeted FOAs

	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

Read FOA very carefully!

New SBIR/STTR Standard Due Dates

See NOT-OD-15-038

Old SBIR/STTR Standard Due Dates

Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
April 5	August 5	December 5

Current SBIR/STTR Standard Due Dates

*** Effective September 5, 2015, *(no AIDS standard due dates)***

Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
September 5	January 5	April 5

Electronic Submission

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

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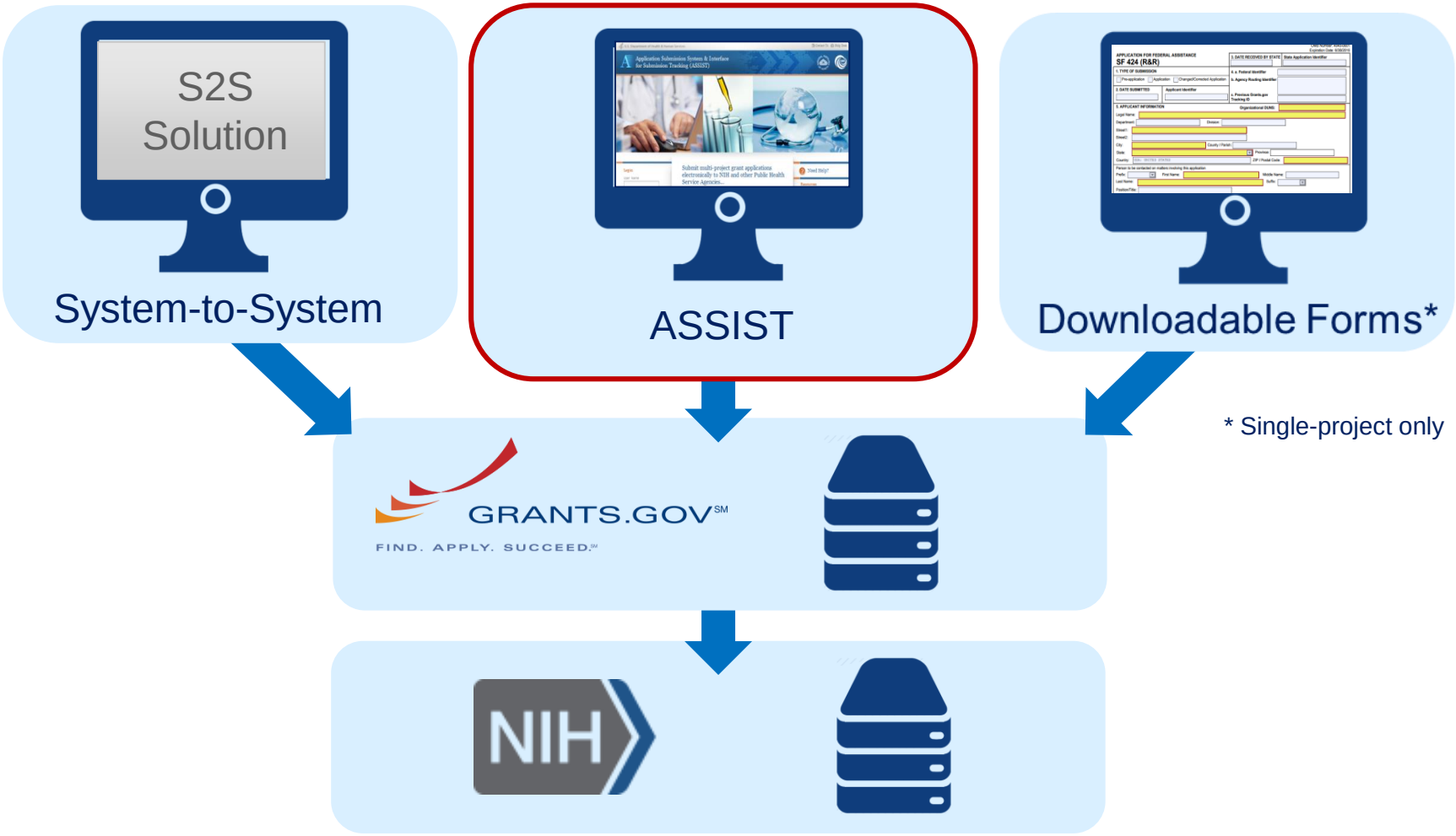
ASSIST – A New Submission Option



* Single-project only

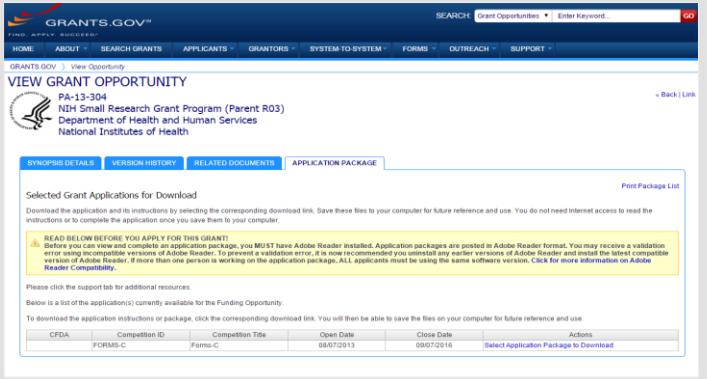
ASSIST is optional, not required!

New FOA "Apply" Buttons

Excerpt from single-project FOA in NIH Guide…

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**



Revised NIH Late Submission Policy

- NOT-OD-15-039 issued on 12/17/2014
- **Two week window** of consideration after the application due date for ALL grant applications, all mechanisms (PA,PAR,RFA)
- SBIR/STTR previously had 1 week window
- Supersedes old policy NOT-OD-11-035

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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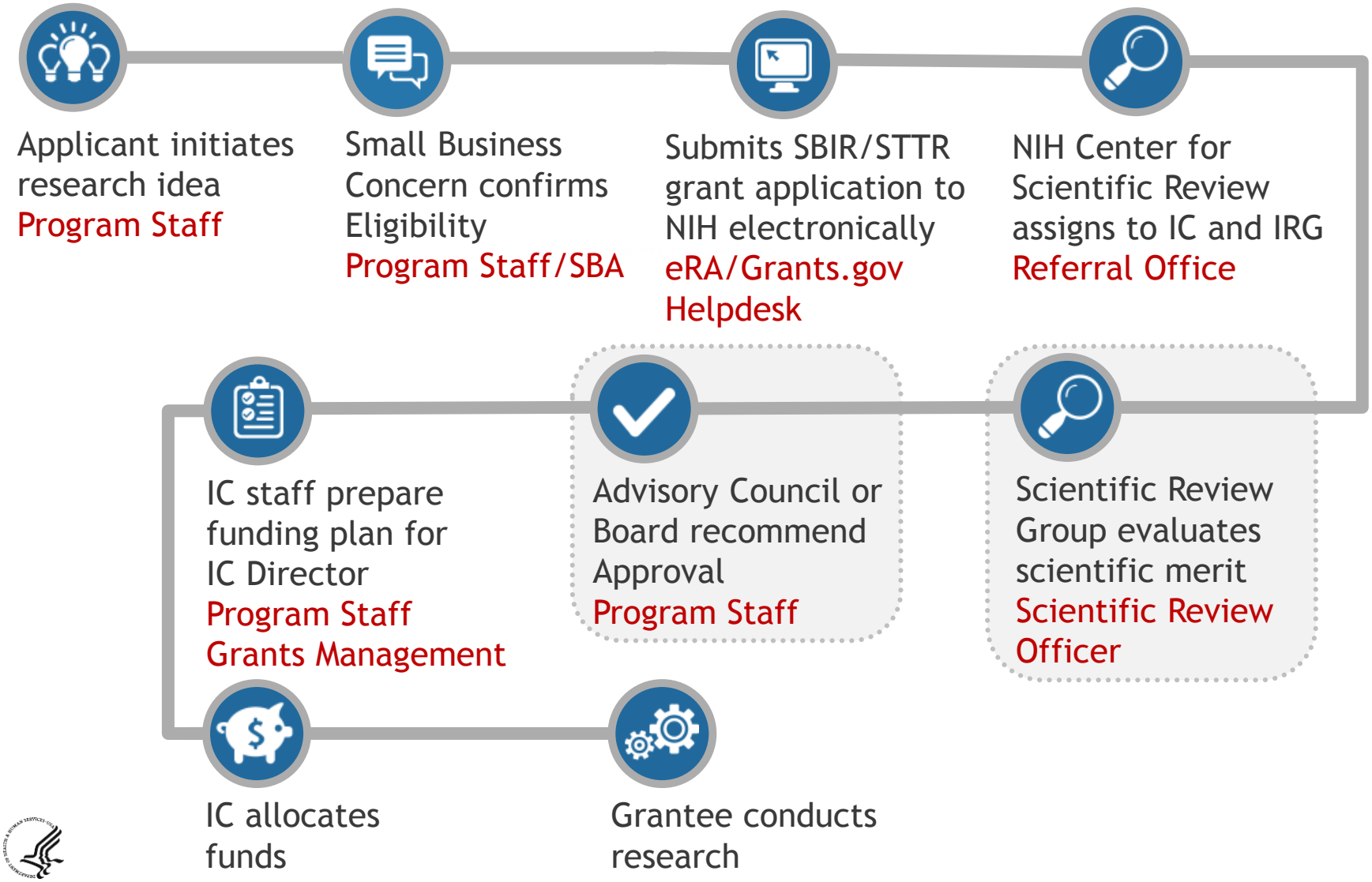
NIH Application & Review Process



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

Common Application Problems

- 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

Most Important Piece of Advice

- Talk to an HHS Program Officer about your application and **SUBMIT EARLY** **(days not hours and minutes)!**
  - Program Officer contact information found on the HHS Agency Contact webpage
  - Questions about who to contact? Email sbir@od.nih.gov

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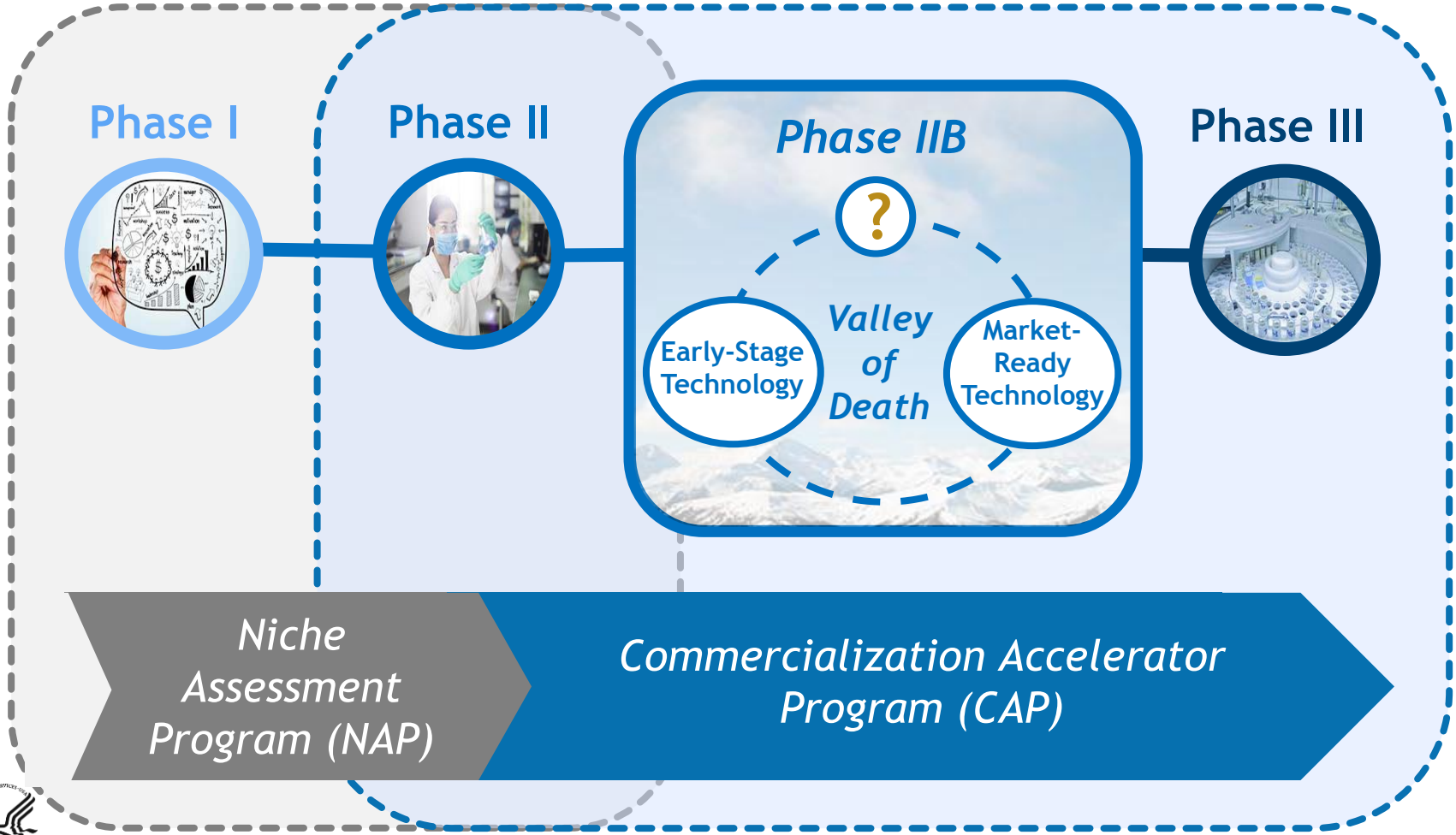
NIH Technical Assistance Programs

Helping companies cross the "Valley of Death"



NIH Technical Assistance Programs

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

Look Towards 2017!

***The 19th Annual will be in Milwaukee, Wisconsin - November 7-9, 2017**

For More Information

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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
- Read our NIH SBIR/STTR Notable Successes
- Connect with Us
- Email: sbir@od.nih.gov