

NATIONAL CANCER INSTITUTE

SBIR

DEVELOPMENT
CENTER

NCI SBIR & STTR OVERVIEW: TRANSLATING CANCER TECHNOLOGIES FROM LAB TO MARKET

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NCI SBIR Development Center**

WHAT ARE SBIR & STTR?

- The NIH SBIR and STTR programs fund early stage small businesses that are seeking to commercialize innovative biomedical technologies.
- A leading source for early stage non-dilutive investment
 - Not a loan, no repayment
 - Intellectual property rights retained by the small business
 - Provides recognition, verification, and visibility
 - Helps provide leverage in attracting additional funding or support

PROGRAM SET ASIDES

❖ **Small Business Innovation Research (SBIR)**

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

Federal agencies with an extramural R&D budget > \$100M

❖ **Small Business Technology Transfer (STTR)**

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

Federal agencies with an extramural R&D budget > \$1B

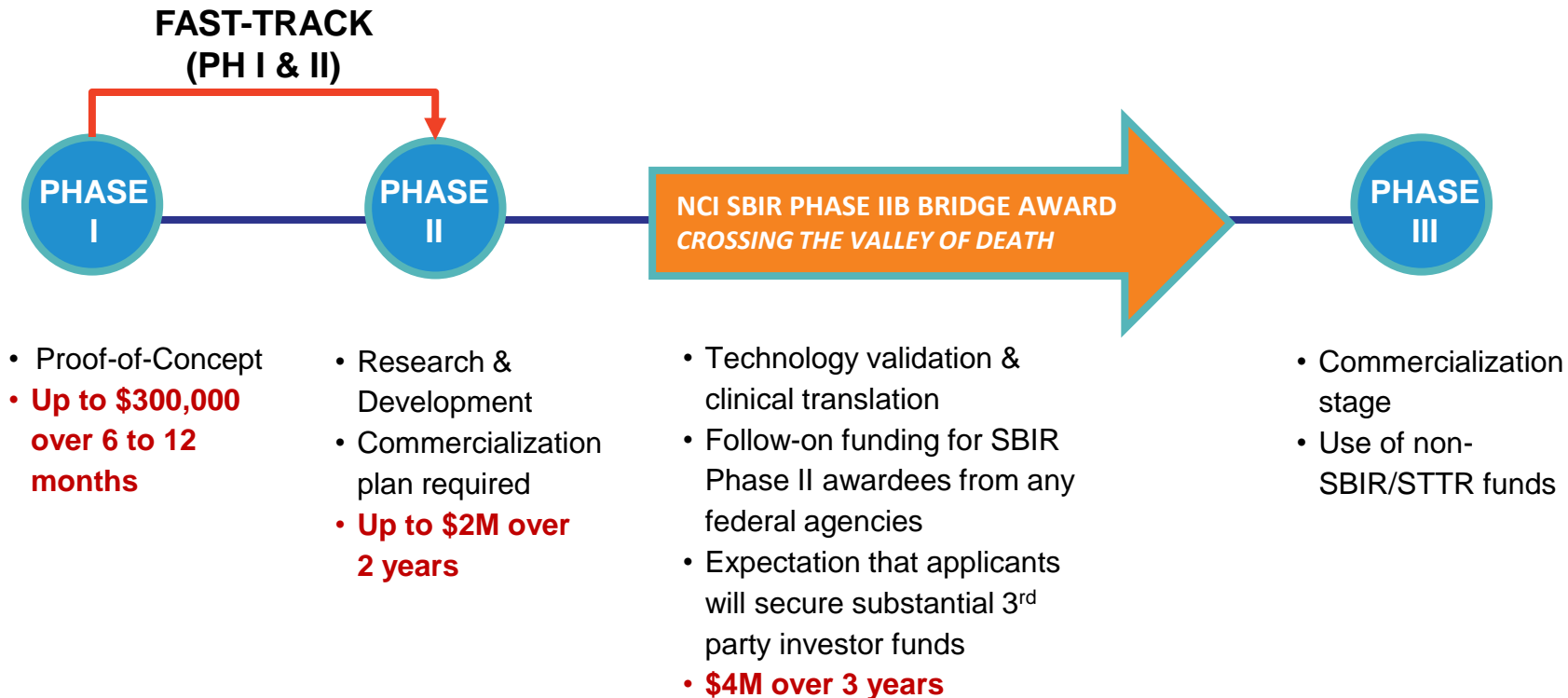
Set Aside

FY16	FY17
3.0%	3.2%
0.45%	0.45%

FY18 ~\$1,073M (NIH)

FY18 ~\$167M (NCI)

THREE-PHASE PROGRAM



ELIGIBILITY

- ✓ Applicant must be a Small Business Concern (SBC)
- ✓ Organized for-profit U.S. business
- ✓ 500 or fewer employees, including affiliates
- ✓ > 50% U.S.- owned by individuals and independently operated

**Award always
made to
small business**

OR

> 50% owned and controlled by another (one) business concern that is > 50% owned and controlled by one or more individuals

OR (SBIR ONLY)

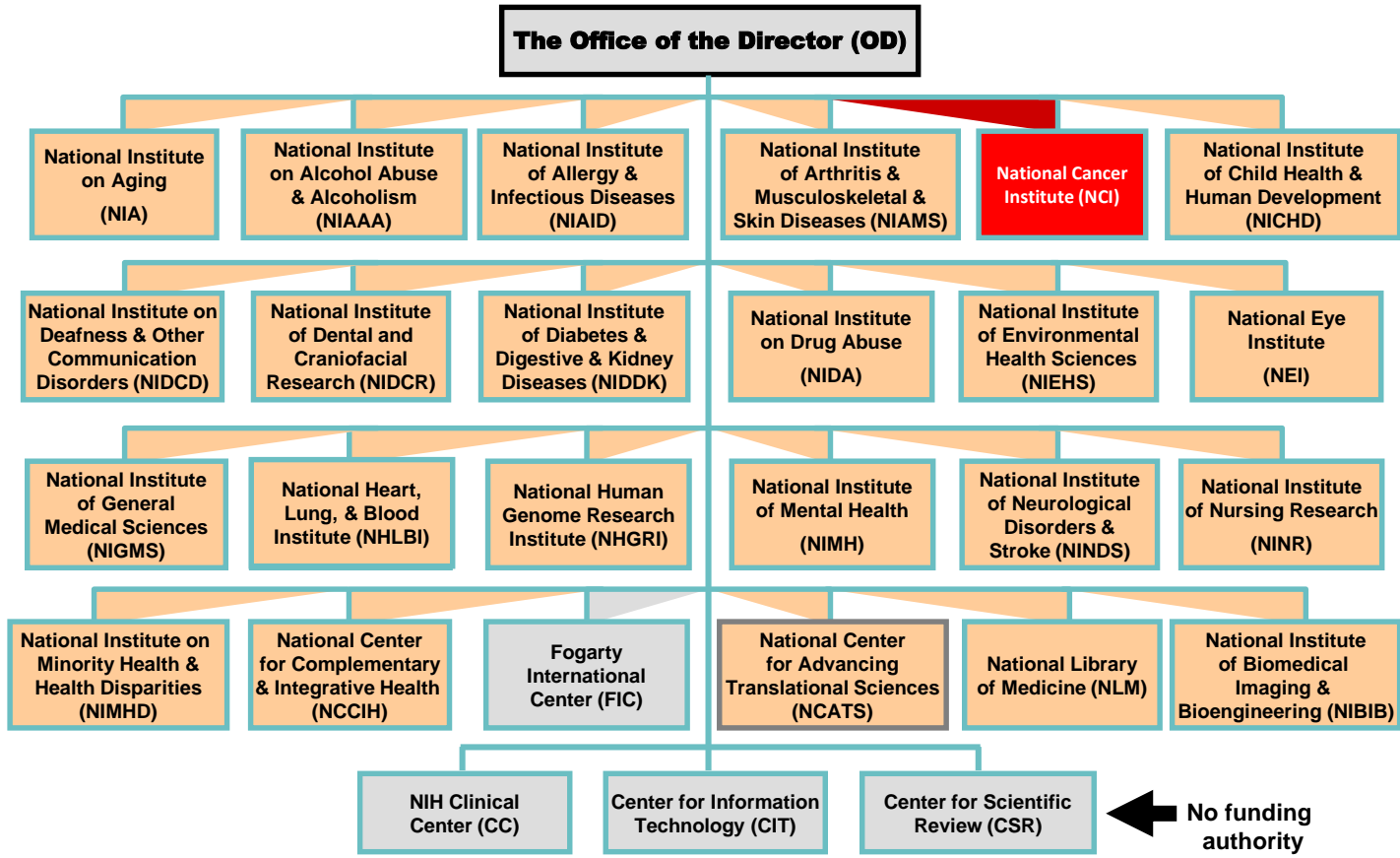
> 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

CRITICAL DIFFERENCES

SBIR	STTR
<p>Permits research institution partners (e.g., universities)</p>	<p>Requires research institution partners (e.g., universities)</p>
<p>Small business concern may outsource ~33% of Phase I activities and 50% of Phase II activities</p>	<p>Minimum 40% of the work should be conducted by the small business concern (for profit), and minimum of 30% by a U.S. research institution (non-profit)</p>
<p>ELIGIBILITY: The PD/PI's primary employment (i.e., >50%) MUST be with the SBC for the duration of the project period</p>	<p>ELIGIBILITY: IP Agreement providing necessary IP rights to the SBC in order to carry out follow-on R&D and commercialization</p>
	<p>PI primary employment not stipulated (min. 10% effort to project)</p>

NIH has 27 Institutes and Centers

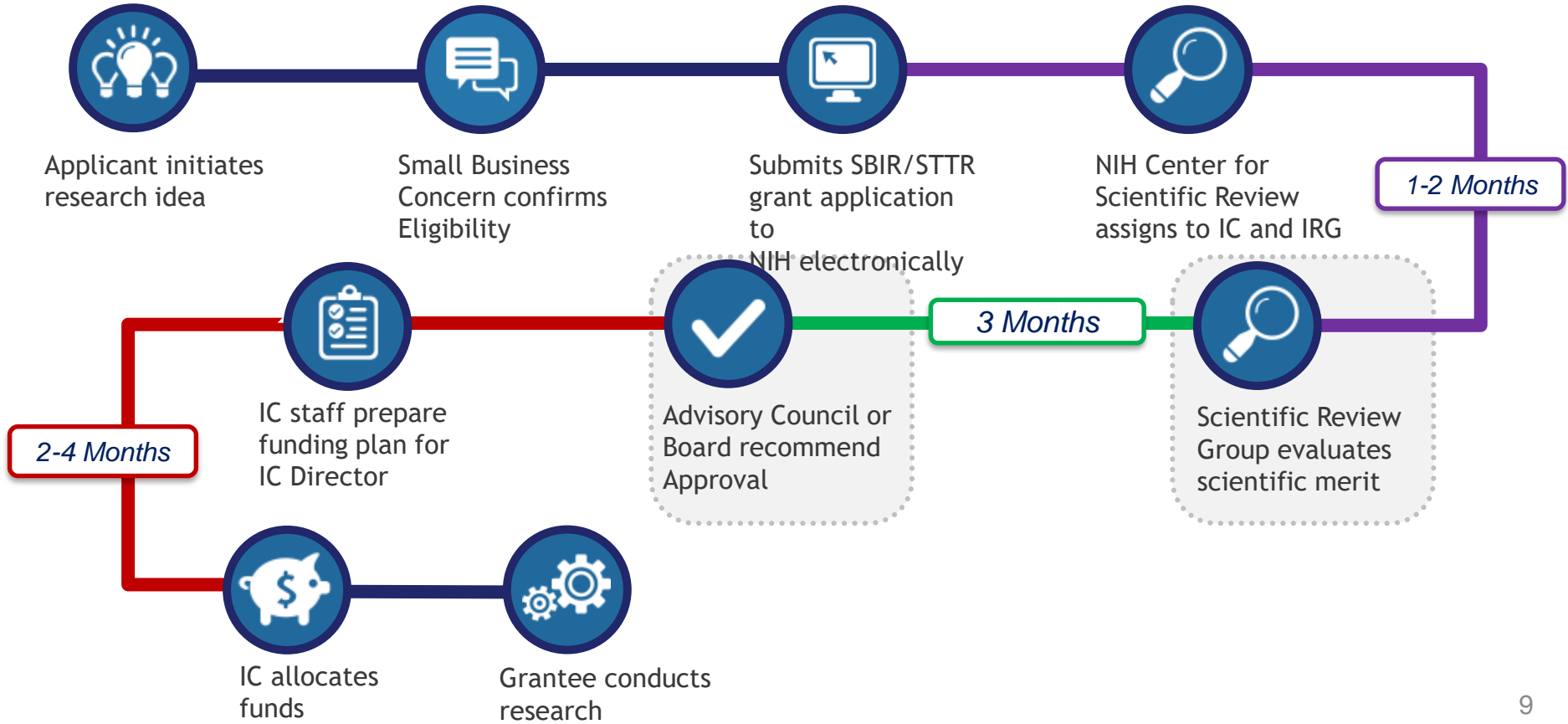
23 “separate” SBIR/STTR Programs



FUNDING OPPORTUNITIES

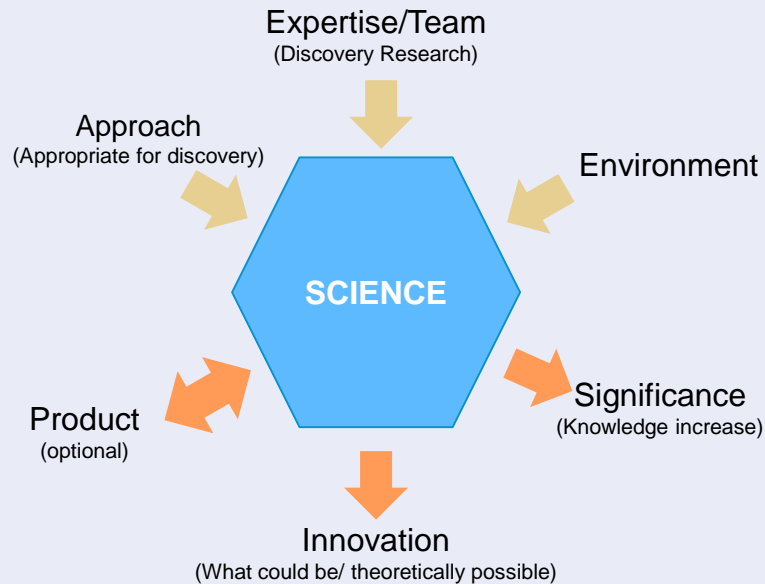
TITLE	SBIR FOA	STTR FOA	RECEIPT DATES
Omnibus Solicitation	PA-18-574 (General) PA-18-573 (Clinical Trial)	PA-18-575 (General) PA-18-576 (Clinical Trial)	September 5; January 5; April 5
SBIR Technology Transfer (technology transfer out of NIH intramural labs)	PA-18-705 (SBIR only)		
Cancer Prevention, Diagnosis, and Treatment Technologies for Low-Resource Settings	PAR-18-801	PAR-18-802	
SBIR IMAT (Innovative Molecular Analysis Technology) Development	PAR-18-303 (SBIR only)		
Development of Highly Innovative Tools and Technology for Analysis of Single Cells	PA-17-147	PA-17-148	
Tools for Cell Line Identification	PA-16-186 (SBIR only)		
Phase IIB Bridge Award Open to federally-funded Phase II awardees	RFA-CA-18-011 (SBIR only)		Expired for 2018
Contract Solicitation	PHS 2019-1		October 22
Administrative Supplement	PA-18-591		Rolling

APPLICATION & REVIEW PROCESS

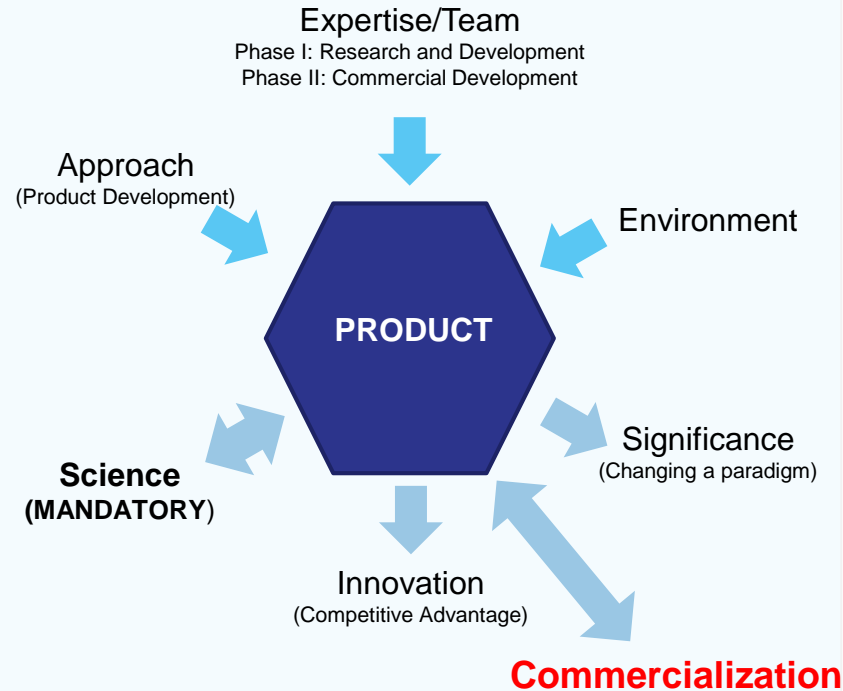


PRODUCT FOCUS

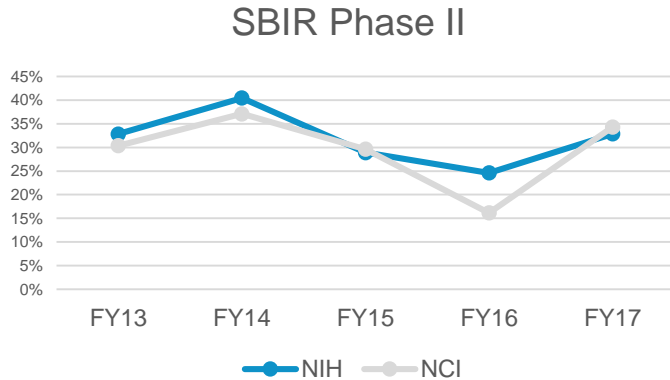
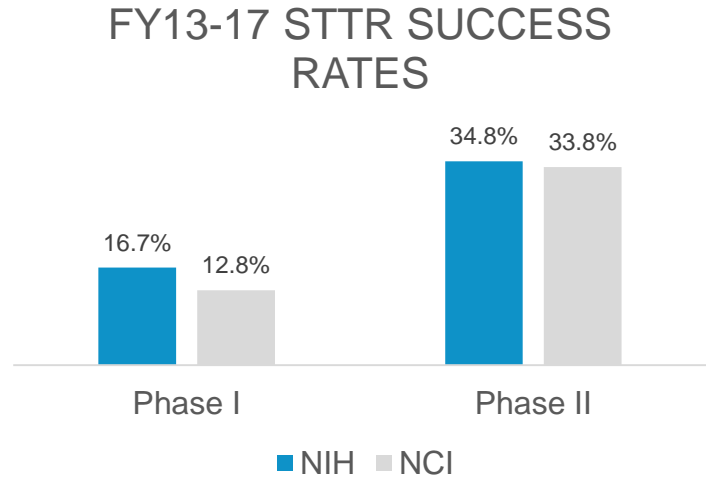
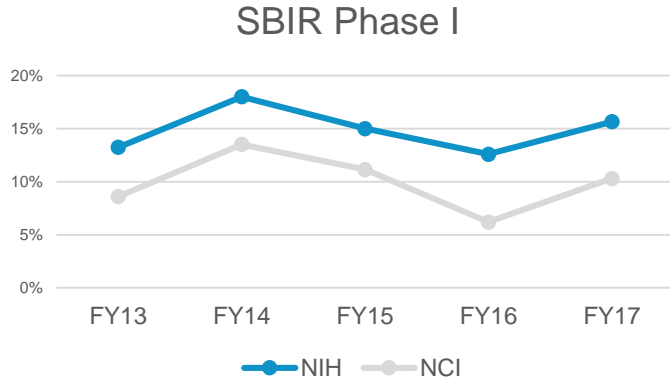
ACADEMIC GRANT



SBIR/STTR GRANT



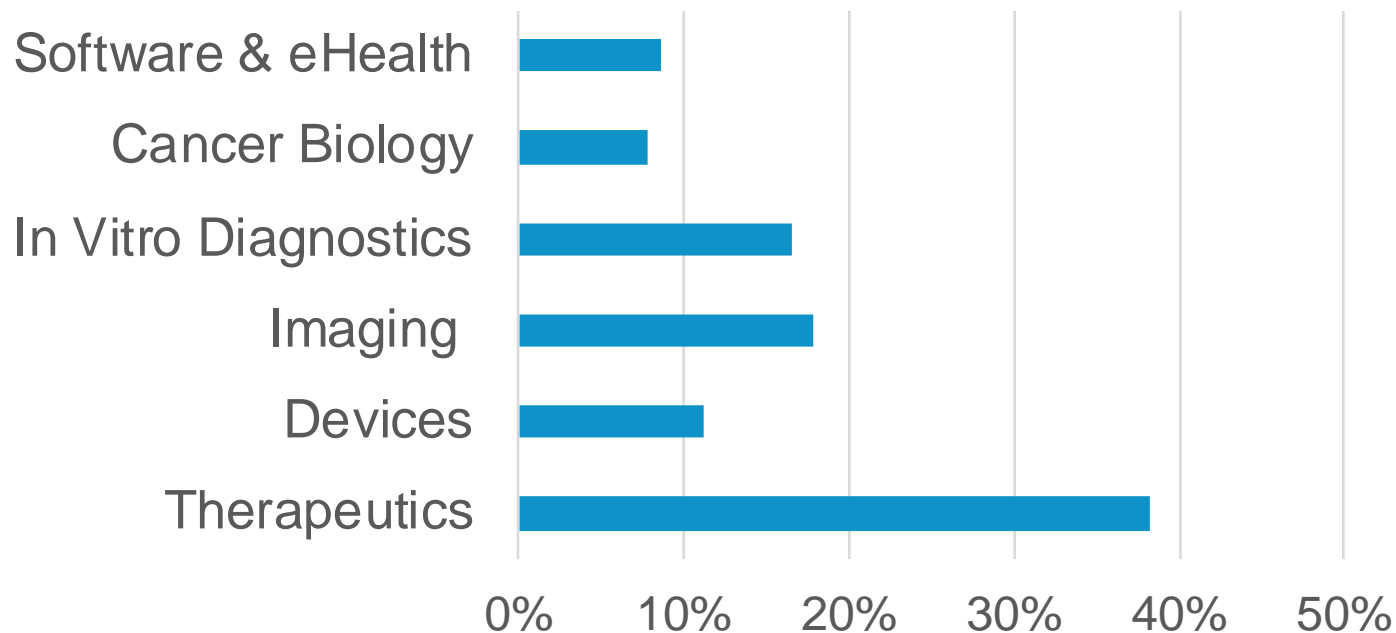
FY13-17 SBIR and STTR SUCCESS RATES



	Phase	Applications Reviewed	Applications Awarded	Success Rate
NIH	Phase I	4,672	778	16.7%
	Phase II	454	158	34.8%
NCI	Phase I	1,087	139	12.8%
	Phase II	68	23	33.8%

SBIR/STTR PORTFOLIO

FY2017 Portfolio (422 Projects)



86% Grants
13% Contracts

49% Phase I
51% Phase II

GRANT vs. CONTRACT

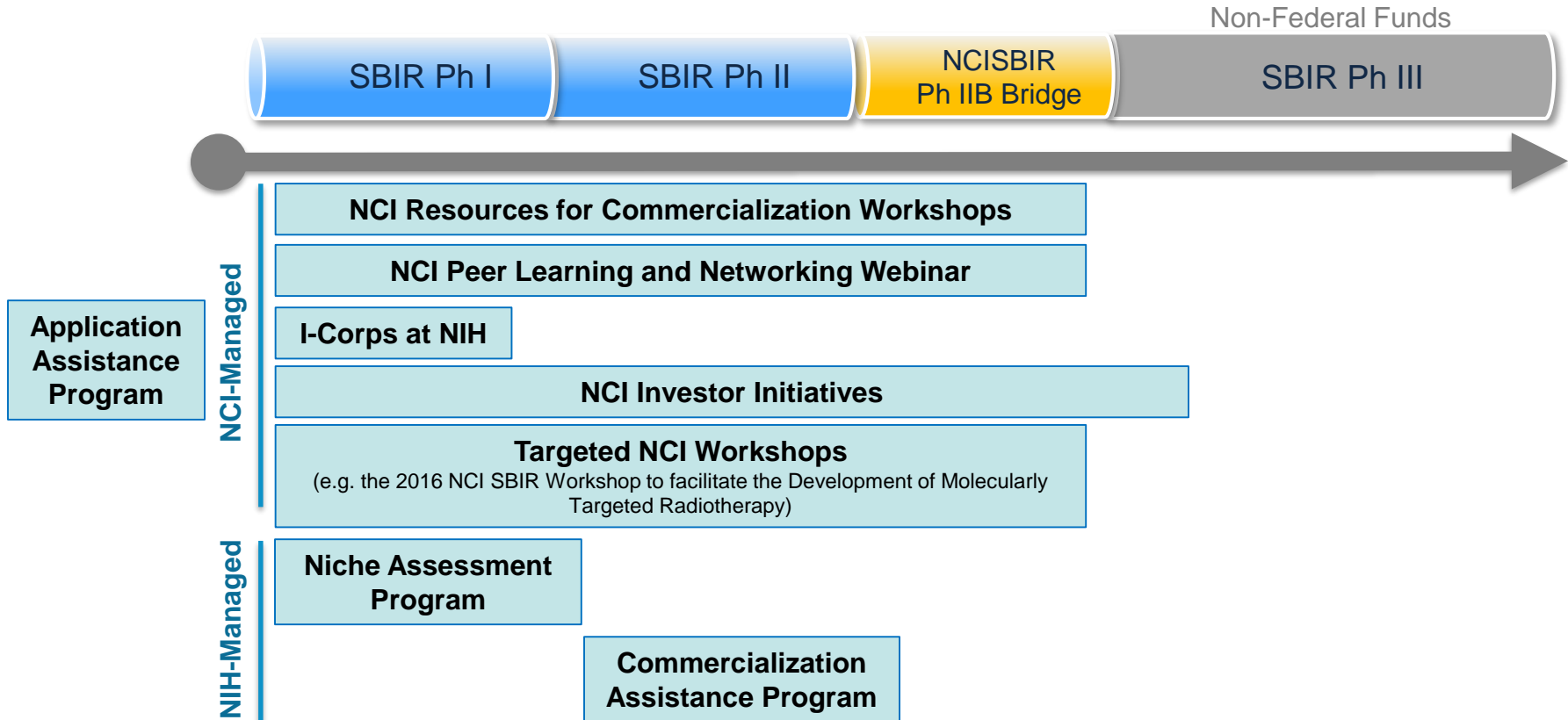
	GRANT	CONTRACT
<i>Scope of the proposal</i>	Investigator-defined within the mission of NIH	Defined by the NIH (focused)
<i>Peer Review Locus</i>	NIH Center for Scientific Review (CSR)	NCI DEA (target 50% business reviewers)
<i>Questions during solicitation period?</i>	May speak with any Program Officer	<u>MUST</u> contact the contracting officer
<i>Receipt Dates</i>	3 times/year for Omnibus	Only ONCE per year
<i>Set-aside of funds for particular areas?</i>	NO	YES
<i>Basis for Award</i>	Based on score during peer review	If proposal scores well during peer review, must then negotiate to finalize deliverables with NIH
<i>Reporting</i>	One final report (Phase I); Annual reports (Phase II)	Kick-off presentation, quarterly progress & final reports

FY19 NCI CONTRACT TOPICS

Topic Title	Fast Track Accepted?
NIH/NCI 382: Integrated Subcellular Microscopy and 'Omics in Cancer Cell Biology	Yes
NIH/NCI 383: Smart, Multi-Core Biopsy Needle	Yes
NIH/NCI 384: Digital Healthcare Platform to Reduce Financial Hardship for Cancer Patients	Yes
NIH/NCI 385: Leveraging Connected Health Technologies to Address and Improve Health Outcomes of Long-Term Cancer Survivors	Yes
NIH/NCI 386: Novel Approaches for Local Delivery of Chemopreventive Agents	Yes
NIH/NCI 387: Multiplexed Preclinical Tools for Longitudinal Characterization of Immunological Status in Tumor and Its Microenvironment	Yes
NIH/NCI 388: In vitro Diagnostic for the Liver Flukes <i>Opisthorchis viverrini</i> and <i>Clonorchis sinensis</i>	Yes
NIH/NCI 389: Development of AI Tools to Understand and Duplicate Experts' Radiation Therapy Planning for Prostate Cancer	No
NIH/NCI 390: Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators	Yes
NIH/NCI 391: Drugs or Devices to Exploit the Immune Response Generated by Radiation Therapy	Yes
NIH/NCI 392: Clinical Trials of Systemic Targeted Radionuclide Therapies (FAST TRACK ONLY)	Fast Track Only
NIH/NCI 393: Sensing Tools to Measure Biological Response to Radiotherapy	Yes
NIH/NCI 394: Combinatory Treatment Modalities Utilizing Radiation to Locally Activate or Release Systemically Delivered Therapeutics	Yes
NIH/NCI 395: Targeted Therapy for Cancer- and Cancer Therapy-Related Cachexia	Yes
NIH/NCI 396: Imaging for Cancer Immunotherapies	Yes

<https://sbir.cancer.gov/funding/contracts/currentcontracts>

NIH & NCI ASSISTANCE: MORE THAN JUST \$\$\$



NCI SBIR PROGRAM STAFF



Michael Weingarten, MA
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NCI SBIR Development Center



Greg Evans, PhD
Lead Program Director
Cancer Biology, E-Health, Epidemiology, Research Tools



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Digital Health, Therapeutics, Biologics, FRAC Workshop



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Imaging, Clinical Trials, Radiation Therapy, Investor Initiatives, FRAC Workshop



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Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells



Christie Canaria, PhD
Program Director
Cancer/Biological Imaging, Research Tools, Devices, I-Corps at NIH, Scientific Communications



Kory Hallett, PhD
Program Director
Monoclonal Antibodies, Immunotherapy, Biologics, and Program Analysis

Let's discuss your project!
Send Specific Aims to ncisbir@mail.nih.gov



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Lead Program Director
Biologics, Small Molecules, Nanotherapeutics, Molecular Diagnostics, Bridge Award



Jian Lou, PhD
Program Director
In-Vitro Diagnostics, Theranostics, early-stage drug development, Bioinformatics, Investor Initiatives



Todd Haim, PhD
Program Director
Small Molecules, Biologics, Immunotherapy, Theranostics, Investor Initiatives, FRAC Workshop



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Cancer Biology, Biologics, Small Molecules, Cell Based Therapies



Ashim Subedee, PhD
Program Director
Cancer Therapeutics and Diagnostics, Imaging, Cancer Prevention and Control, Digital Health, Investor Initiatives

Learn More

http://sbir.cancer.gov



Leading small business innovation and commercialization in the fight against cancer

What are the NCI SBIR & STTR Programs?

The SBIR & STTR Programs are one of the largest sources of early stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities.

[Learn more about the programs >](#)

Resources For



Applicants



Awardees



Investors

Success Stories

Learn how NCI SBIR & STTR Programs have helped small businesses with funding awards that help advance cancer research.

Latest Announcements

Sept 8: SBIR & STTR Omnibus Solicitation & Grants Due

September 1, 2015

GRANT DEADLINE APPROACHING: SEPTEMBER 8, 2015 (September 5 is a weekend and September 7 is a Federal Holiday) for SBIR & STTR Omnibus Solicitations (Phase I, Phase II, Fast Track, and Direct to Phase II), plus "Single Cell" PA-13-140.

HHS SBIR Contract RFP Informational Webinar Materials Now Available!

August 28, 2015

Applying to the FY2016 Contract Solicitation? Check out these webinar materials for helpful information and tips.

New Contract Funding Opportunities Available!

http://sbir.nih.gov

SBIR/STTR HOME

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ELECTRONIC SUBMISSION PROCESS

SUCCESS STORIES

CONTACT US

ENGAGE AND CONNECT



CELEBRATING
10
YEARS

NIH Technical Assistance Programs

- Niche Assessment Program
- Commercialization Assistance Program (CAP)

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!

SBIR

The NIH SBIR program funds early stage small businesses that are seeking to commercialize innovative biomedical technologies. This competitive program helps small businesses participate in federal research and development, develop life-saving technologies, and create jobs.

HHS SBIR/STTR COMPONENT PROGRAM LINKS

NEWS

The Niche Assessment Program is Now Closed [NEW](#)

Feb 11, 2015

We're Heading to Seattle for the 17th Annual NIH SBIR/STTR Conference! [NEW](#)

Feb 10, 2015

HHS-NIH SBIR Webinar, hosted by NCT22 Now Posted [NEW](#)

Feb 9, 2015

Clarification about the New Standard Due Dates for All HHS SBIR/STTR Grant Applications

Dec 22, 2014

Important Change in Standard Due Dates for All HHS SBIR/STTR Grant Applications

Dec 17, 2014

THANKS FOR YOUR ATTENTION!

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