

# NCI SBIR & STTR

Funding, mentoring & networking assistance for  
next-generation life science technologies

*Oct 12, 2016*

***Amir Rahbar, PhD, MBA***  
***Program Director***

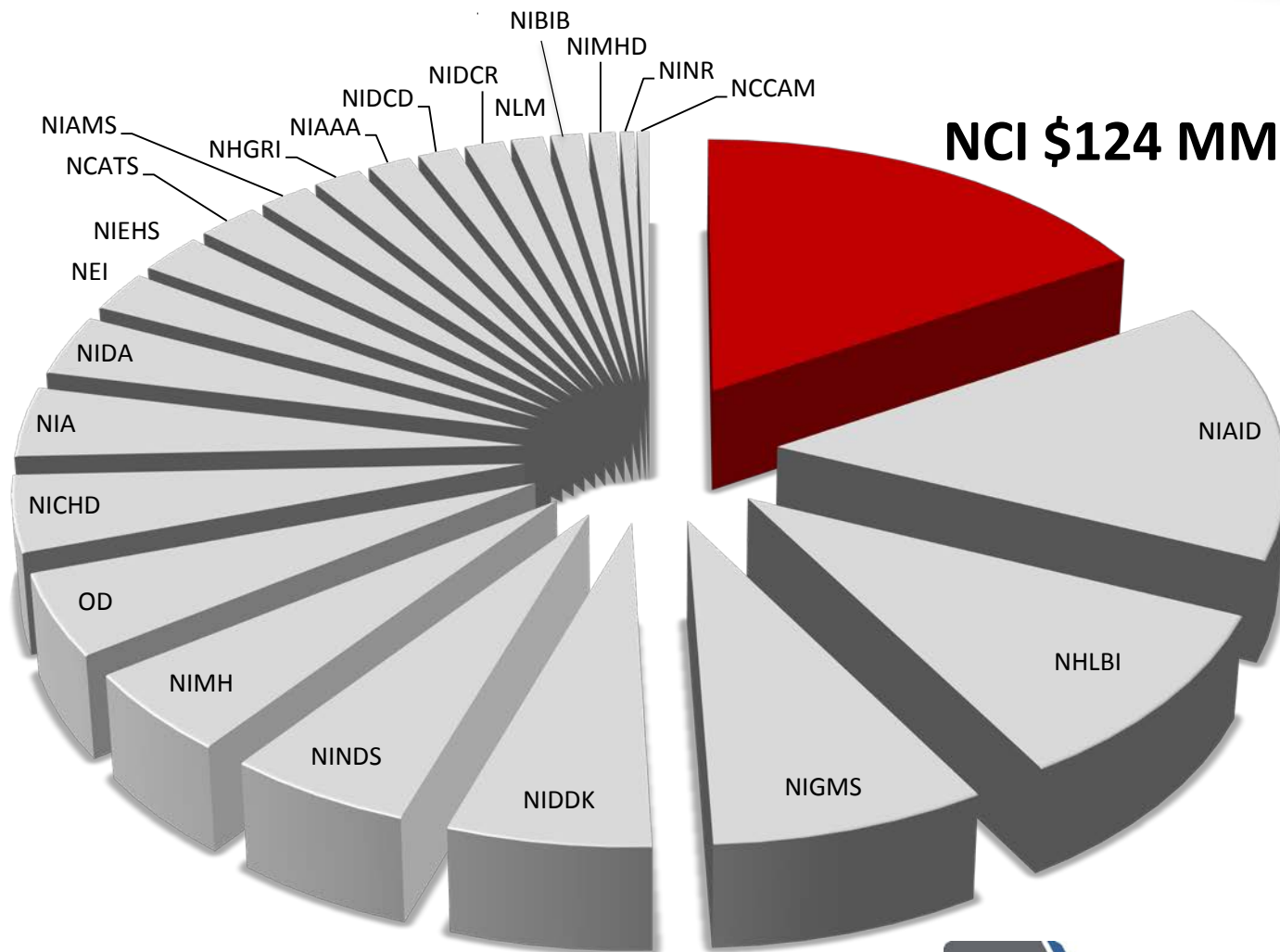
***National Cancer Institute SBIR Development Center***



	Set Aside	
	(FY16)	(FY17)
<b>➤ Small Business Innovation Research (SBIR)</b>		
Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization	3.0%	3.2%
<i>Federal agencies with an extramural R&amp;D budget &gt; \$100M</i>		
<b>➤ Small Business Technology Transfer (STTR)</b>		
Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization	0.45%	0.45%
<i>Federal agencies with an extramural R&amp;D budget &gt; \$1B</i>		

~\$877M annually at NIH  
~\$136M annually at **NCI**

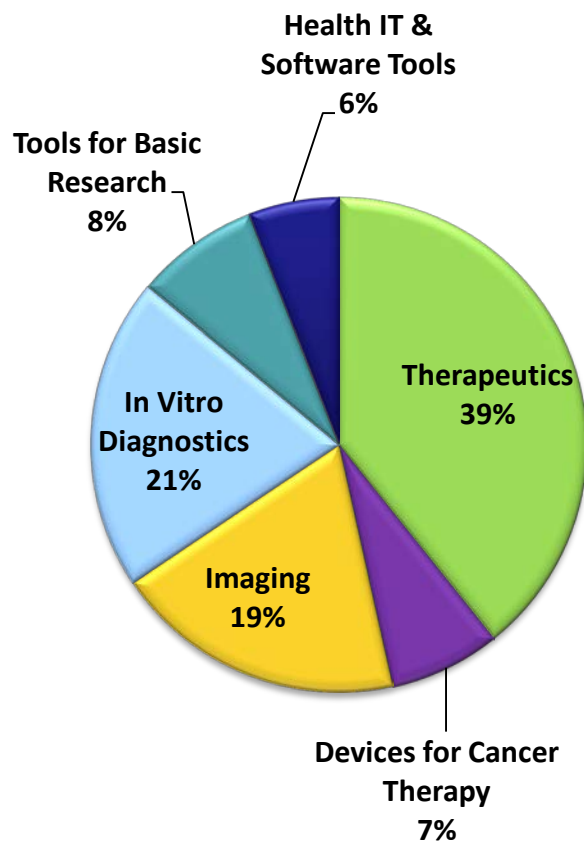
# NIH FY2015 Small Business Funding (\$786 M)



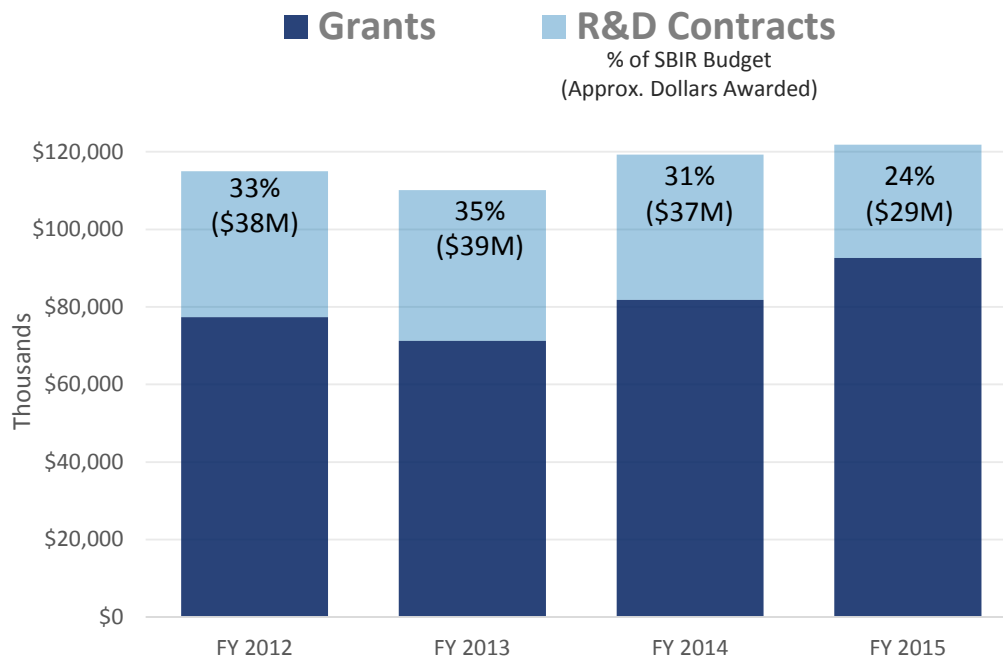
# NCI SBIR/STTR Portfolio



Major Portfolio Areas  
(FY 2015)



NCI SBIR Funding Mechanisms



## FY16 SBIR/STTR Funding

**\$877M at NIH**

**\$136M at NCI**

# SBIR Eligibility Requirements

*New Rules starting 1/28/13*



- Applicant is a Small Business Concern (SBC)
- Organized for-profit U.S. business
- 500 or fewer employees, including affiliates
- PI's primary employment (>50%) must be with the SBC at time of award & for duration of project
- **> 50% U.S.- owned by individuals** and independently operated\*

**OR**

- > 50% owned and controlled by other business concern/s that is/are > 50% owned and controlled by one or more individuals\*

**OR**

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

\*Formerly  $\geq 51\%$ ; \*New rule starting 1/28/13, NIH SBIR only

- **Applicant is a Small Business Concern (SBC)**
- **Organized for-profit U.S. business**
- **Formal cooperative R&D effort**
  - Minimum 40% by small business
  - Minimum 30% by US research institution
- **US Research Institution: college or university; non-profit research organization; Federally-Funded R&D Center (FFRDC)**
- **Principal Investigator's primary employment may be with either the SBC or the research institution**
- **SBC must have right to IP to carry out follow-on R&D and commercialization**



# SBIR vs. STTR: Which Program is Best for You?



	<u>SBIR</u>	<u>STTR</u>
Principal Investigator	Primary employment <b>must</b> be with small business	PI may be employed by either small business or research institution, and must commit minimum of 10% effort to project
Research Partner	Permits partnering <i>Small business must do 67% Phase I, 50% Phase II</i>	<b>Requires</b> partnering with US research institution <i>Small business min. 40%, Research institution min. 30%</i>

- Small Business Concern is ALWAYS the Applicant/Awardee Organization
- Funding rates vary annually based primarily on application numbers
- The best choice is the fit for your budget and leadership structure

# NIH SBIR & STTR: Three-Phase Program



## Phase I

- Proof-of-Concept study
- \$225,000 over 6 months (SBIR) or 1 year (STTR)

**Direct to Phase II  
(Skip Phase I)**

- Commercialization stage
- Use of non-SBIR/STTR funds

**Phase I  
FEASIBILITY**

**Phase II  
DEVELOPMENT**

**Phase III  
COMMERCIALIZATION**

**Fast Track Application  
Combined Phase I & II**

## Phase II

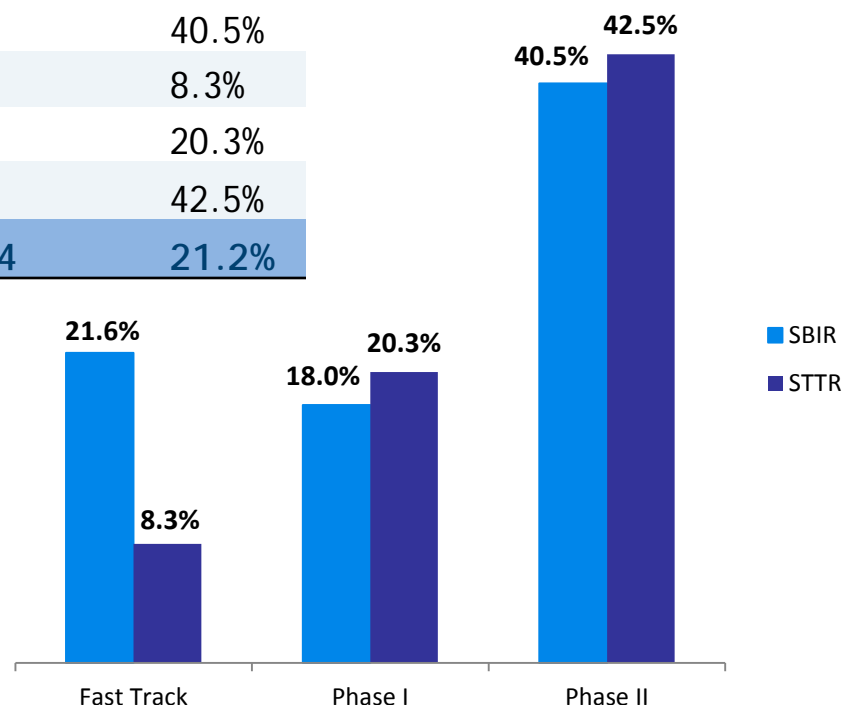
- Research & Development
- Commercialization plan required
- \$1.5 million over 2 years




# 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](http://report.nih.gov/success_rates/index.aspx)

 U.S. Department of Health & Human Services

 National Institutes of Health

OER HOMEABOUT GRANTSFUNDINGFORMS & DEADLINESGRANTS POLICYERANEWS & EVENTSABOUT OER

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

Printer Friendly | Text Size A- A+

SEARCH

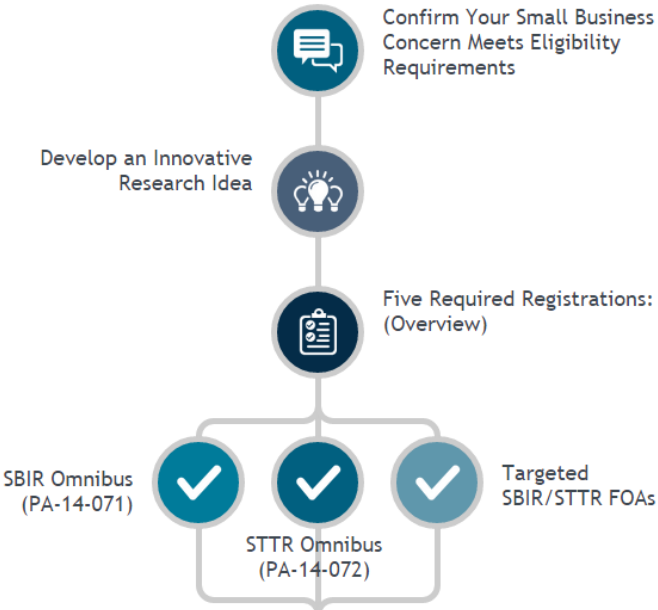
**SBIR/STTR HOME**  
ABOUT  
FUNDING  
APPLY  
REVIEW  
POLICY  
TECHNICAL ASSISTANCE  
RESOURCES  
STATISTICS AND SUCCESSES  
ENGAGE AND CONNECT  
**New to SBIR/STTR**  
WHERE TO START  
NIH SBIR/STTR REAUTHORIZATION IMPLEMENTATION  
**REPORT FRAUD, WASTE AND ABUSE**  
**FREQUENTLY ASKED QUESTIONS**

SBIR/STTR Home > About > SBIR/STTR Application Process Infographic


## 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**



```
graph TD; A[Develop an Innovative Research Idea] --> B[Confirm Your Small Business Concern Meets Eligibility Requirements]; B --> C[Five Required Registrations: (Overview)]; C --> D[SBIR Omnibus (PA-14-071)]; C --> E[STTR Omnibus (PA-14-072)]; C --> F[Targeted SBIR/STTR FOAs]; D --> G[ ]; E --> G; F --> G; G --> H[ ]; style G fill:none,stroke:none; style H fill:none,stroke:none;
```

 @NCISBIR


Leave Feedback: [bit.ly/NCIsbirFeedback](http://bit.ly/NCIsbirFeedback)

- One of the largest sources of seed funding for innovative technology development by small businesses
- **Not a Loan**
  - No repayment is required
  - Doesn't impact stock or shares in any way (i.e., non-dilutive)
- Intellectual property rights retained by the small business
- Provides recognition, verification, and visibility
- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)

- VC-backed companies (VCOC, hedge fund, private equity firms) **CAN NOW** apply (NIH SBIR only).
- **Direct to Phase II Pilot Program now active**
- **Increased caps for pre-approved waiver topics (see FOA) – Ph I \$300K, Ph II \$2M**
  - Otherwise: Ph I \$225K, Ph II \$1.5M

- **Switching between SBIR and STTR mechanisms**
  - Applicants can apply for Phase II SBIR funding based on Phase I STTR award or vice versa.
  - Applicants can apply for Phase IIB SBIR funding based on Phase II STTR award or vice versa.
- **Applicants can request \$5000 in Technical Assistance, beyond award caps.**
  - Regulatory consultant
  - Reimbursement consultant

<http://grants.nih.gov/grants/funding/sbir/reauthorization.htm>



The screenshot shows the NIH SBIR/STTR Reauthorization Act of 2011 website. The header includes the Department of Health & Human Services logo and the URL www.hhs.gov. A search bar is located in the top right corner. The main navigation menu includes links to Funding, Forms & Deadlines, Grants Policy, News & Events, About OER, and NIH Home. The main content area features the title "SBIR/STTR Reauthorization Act Of 2011: NIH Implementation Of Key Changes (What to Expect and When)" and a paragraph explaining the changes. A list of key change areas is provided, including Funding, Eligibility, Streamlining the Award Process, Data & Reporting, New Measures to Guard Against Fraud, Waste, Abuse, and Increased Support for Commercialization. A sidebar on the right contains a link to the SBIR/STTR Reauthorization Act of 2011 Home page and a list of key change areas.

Health & Human Services [www.hhs.gov](http://www.hhs.gov)

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## 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.

1. [Funding](#)
2. [Eligibility](#)
3. [Streamlining the Award Process](#)
4. [Data & Reporting](#)
5. [New Measures to Guard Against Fraud, Waste, Abuse](#)
6. [Increased Support for Commercialization](#)

For more information regarding SBA's implementation plan, read Sean Greene's (Associate Administrator for Investment and the Special Advisor for Innovation at SBA) [blog](#) which includes links to the recently released Policy Directives, a synopsis of key changes, and FAQs.

Matthew E. Portnoy, Ph.D.  
NIH SBIR/STTR Program Coordinator  
Office of Extramural Programs, NIH  
[sbir@od.nih.gov](mailto:sbir@od.nih.gov)

### SBIR/STTR Reauthorization Act Of 2011 Home

- [Funding](#)
- [Eligibility](#)
- [Streamlining the Award Process](#)
- [Data & Reporting](#)
- [New Measures to Guard Against Fraud, Waste, Abuse](#)
- [Increased Support for Commercialization](#)



# Application Timeline: Its Getting Faster!



OLD TIMELINE: 8 -16 months from application to award

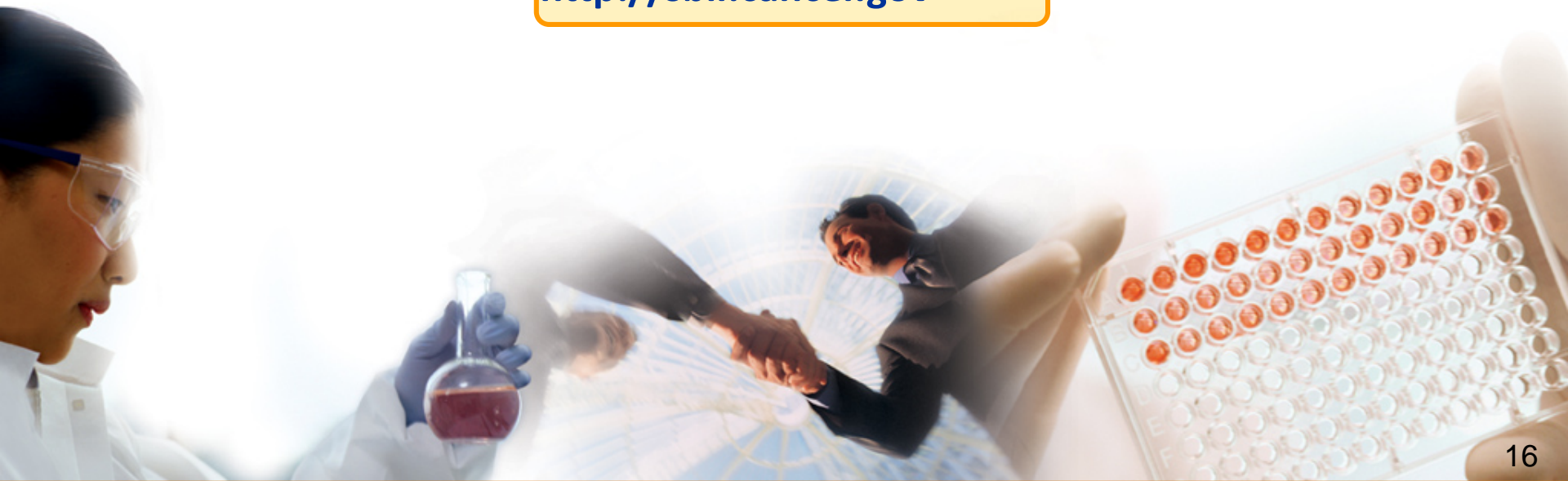
Due Date	Scientific Review	Council Review	Award Date (earliest)
April 5	July	October	December
August 5	October	January	April
December 5	March	May	July

**NEW TIMELINE GOAL:** Funding of > 50% of applications within 6 months

Standard Due Date	Scientific Review	Council Review	Award Date (earliest)
September 5	December	January	March
January 5	March	May	June
April 5	June	September	September

# The NCI SBIR Development Center

<http://sbir.cancer.gov>



# NCI SBIR Development Center Program Staff



**Michael Weingarten, MA**  
*Director*  
NCI SBIR Development Center



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



**Patricia Weber, DrPH**  
*Program Director*  
Digital Health, Therapeutics, Biologics, SBIR Investor Forum, FRAC Workshop



**Deepa Narayanan, MS**  
*Program Director*  
Cancer Imaging, Clinical Trials, Radiation Therapy, SBIR Investor Forum, FRAC Workshop



**Ming Zhao, PhD**  
*Program Director*  
Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells



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



**Kory Hallett, PhD**  
*AAAS Science & Technology Policy Fellow*  
Monoclonal Antibodies, Immunotherapy, Biologics, and Program Analysis



**Andrew J. Kurtz, PhD**  
*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, FRAC Workshop



**Todd Haim, PhD**  
*Program Director*  
Small Molecules, Biologics, Immunotherapeutics, Theranostics, SBIR Investor Forum, FRAC Workshop



**Amir Rahbar, PhD, MBA**  
*Program Director*  
In-Vitro Diagnostics, Biologics, Therapeutics, Proteomics, SBIR Investor Forum



**Jonathan Franca-Koh, PhD, MBA**  
*Program Director*  
Cancer Biology, Biologics, Small Molecules, Cell Based Therapies

**ncisbir@mail.nih.gov**

**sbir.cancer.gov**

**@NCIsbir**

Leave Feedback: [bit.ly/NCIsbirFeedback](http://bit.ly/NCIsbirFeedback)

- Play active role in seeding emerging technology areas
- Coach applicants in preparation of funding applications
- Provide central oversight of all 400+ NCI-funded SBIR and STTR projects (Program Director role)
- Conduct regular outreach events all over the U.S. (with state-based, BIO-like organizations)
- Maintain a network of investors, and broker personal connections between NCI SBIR companies and potential third-party investors/strategic partners

- **Omnibus Solicitations (Phase I, Phase II, FastTrack)**
  - [PA-16-302](#) (SBIR) and [PA-16-303](#) (STTR)
- **Direct to Phase II Solicitation**
  - [PAR-14-088](#) (SBIR only)

**We encourage applications for any topic  
within the NIH mission**

**Due September 5, January 5, April 5**

**Goal:** To encourage SBIR grant applications that transfer technology out of NIH intramural research labs and into the private sector.

- Royalty-free, non-exclusive patent license agreement for internal research use will be granted to the SBC upon award
- Collaborate with NIH intramural researchers (no SBIR funds may go back to intramural investigators)
- For a searchable listing of NCI inventions: <http://www.ott.nih.gov/ic/nci>

Standard due dates apply. Expires September 6, 2018.

**Contact Dr. Christie Canaria:** [christie.canaria@nih.gov](mailto:christie.canaria@nih.gov) and  
**John D. Hewes, NCI Tech Transfer Center:** [john.hewes@nih.gov](mailto:john.hewes@nih.gov)  
<http://grants.nih.gov/grants/guide/pa-files/PA-15-354.html>



**Goal:** To support small businesses that propose development of a broad base of innovative technologies in biomedical computing, informatics, and Big Data Science that will support rapid progress in areas of scientific opportunity in biomedical research.

- SBIR FOA: [PA-14-154](#)
- STTR FOA: [PA-14-157](#)
- Direct-to-Phase II FOA: [PA-15-288](#)

Standard due dates apply. Expires April 6, 2017.

**Contact Dr. Jonathan Franca-Koh: [jonathan.franca-koh@nih.gov](mailto:jonathan.franca-koh@nih.gov)**

Phase I  
FEASIBILITY

Phase II  
DEVELOPMENT

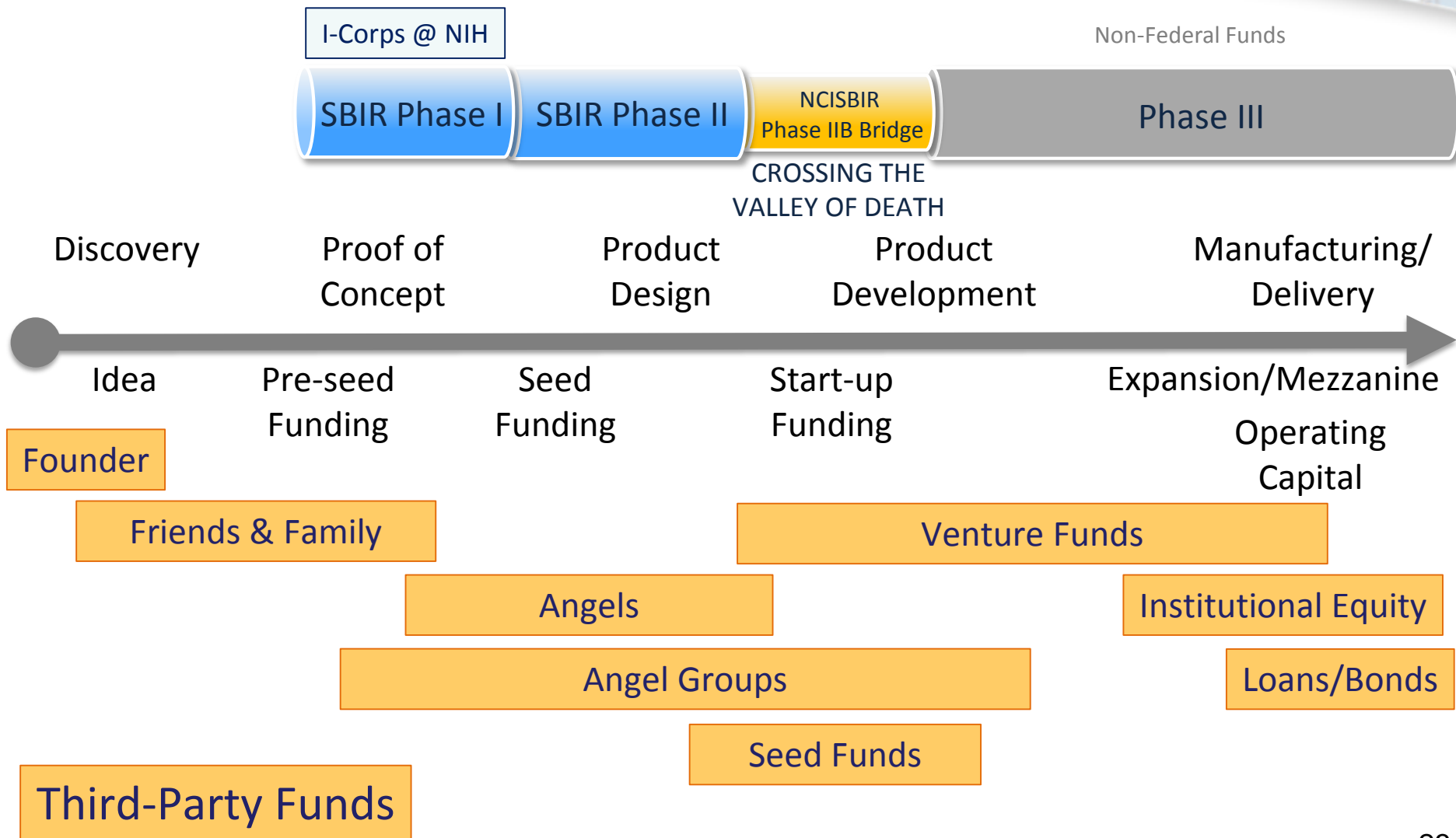
NCI SBIR Phase IIB Bridge Award

CROSSING THE VALLEY OF DEATH

Phase III  
COMMERCIALIZATION

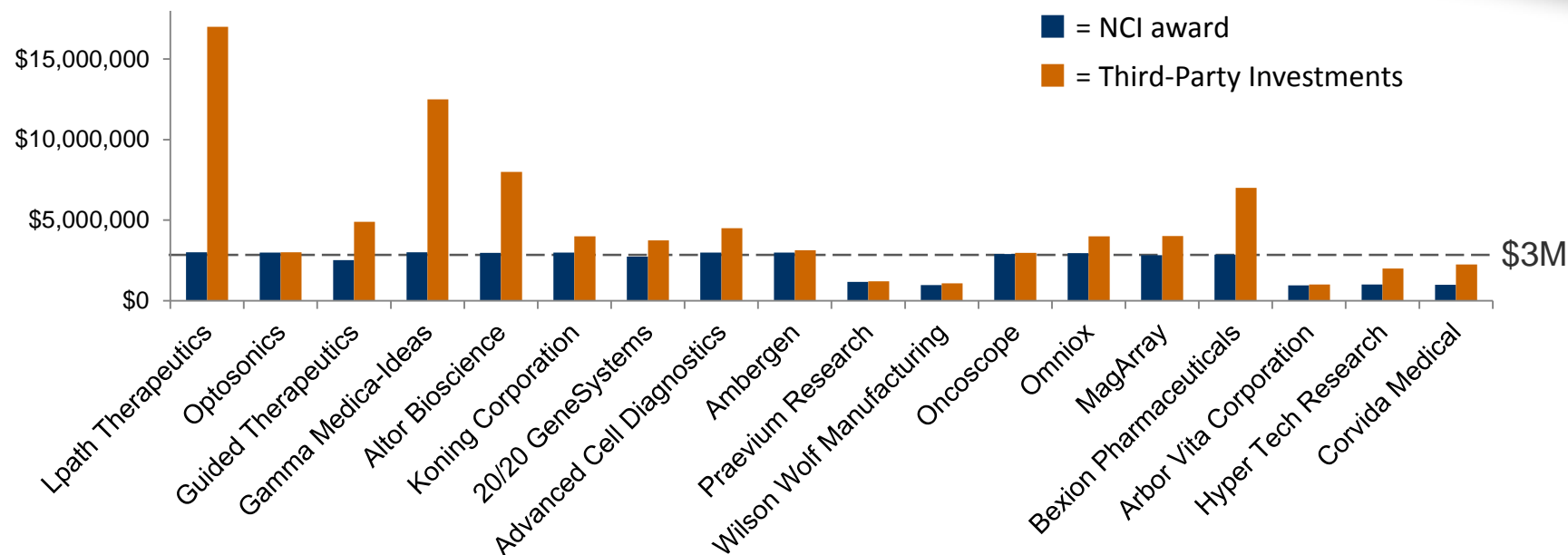
- Provides up to \$1M per year for up to 3 years
- Open to any NIH-funded Phase II awardees with projects relevant to NCI mission
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners earlier in the development process
- Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e.,  $\geq 1:1$  match)

# NIH SBIR/STTR Resources



# 18 Bridge Awards

FY2009 – FY2014



NCI Total	\$42.8 M
Third-Party Investments	\$86.3 M
Leverage	> 2 to 1

→ {  
~ 40% Venture Capital  
~ 35% Strategic Partners  
~ 25% Angels & Individuals

# 4 Cancer-Focused NCI SBIR Investor Forums- 2009, 2010, 2012, and 2014



LEAP OF FAITH® TECHNOLOGIES

MagArra<sup>®</sup>

Omniox  
Targeted oxygen delivery

**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**

National Cancer Institute  
**SBIR Investor Forum**



**NOVEMBER 9, 2010**  
9:00 AM – 6:00 PM PST

**STANFORD UNIVERSITY  
FRANCES C. ARRILLAGA  
ALUMNI CENTER**  
326 Galvez Street  
Stanford, CA, USA 94305 – 6105

**bio center** SAN JOSE

National Cancer Institute  
**2012 NCI SBIR  
Investor Forum**



**APRIL 18, 2012**  
Agilent Technologies,  
Aristotle Room  
5301 Stevens Creek Blvd  
Santa Clara, CA 95051

**FNIH**  
Foundation for the  
National Institutes of Health

**PRE SCIENCE  
INTERNATIONAL**

**SBIR & STTR**

**NCI SBIR  
Investor Forum**

**November 13, 2014**

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



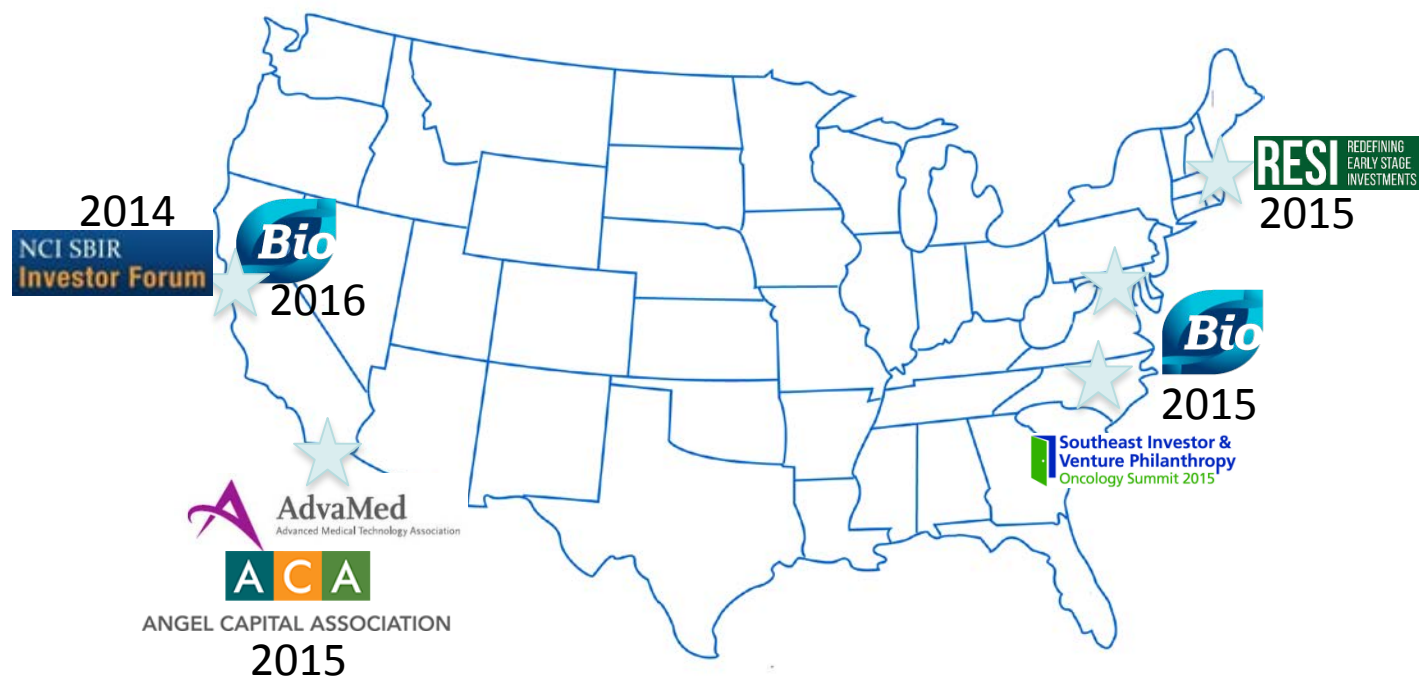
Venrock

SOFINNOVAVENTURES

Genentech  
A Member of the Roche Group



## Leveraging existing investor and partnering events





# Company Selection Based on Investor Reviews



- External Investor based Review Panel consists of 50+ investors and strategic industry partners.
  - Includes representatives from Pfizer, BMS, J&J, GE Ventures, Varian, Bayer, Venrock, Arch Venture Partners, Soffinova and many more.
- Facilitate meetings between reviewers & companies if reviewers are interested.
- Offer feedback to companies from these investors.
- 100+ companies reviewed in the last investor review, around 30 companies selected for showcase events based on reviewer recommendation.

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

<http://sbir.cancer.gov/programseducation/fracworkshop>

- May 24-25, 2016 at NCI Shady Grove
- Speakers from FDA, CMS, USPTO, and across NIH
- Panels on other sources of federal funding, resources & collaborative programs at NIH, and unique life science investment organizations
- One-on-one meetings with program directors and speakers

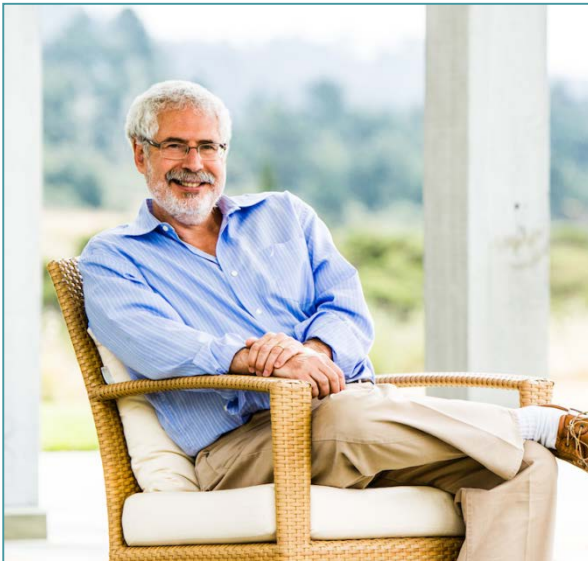
A map of the United States with state boundaries outlined in blue. Orange stars are placed on the map to indicate the locations of 2019 outbreaks. The stars are located in the following states: Washington, California, Nevada, Arizona, New Mexico, Colorado, Kansas, Oklahoma, Texas, Missouri, Illinois, Indiana, Michigan, Ohio, Pennsylvania, New York, Vermont, New Hampshire, Maine, Florida, and Georgia.

## Program for SBIR Phase I grantees to help:

- Define the value proposition (e.g., clinical utility) **early** before spending millions – saves time AND money
- Assess IP and regulatory risk before design and build
- Better understand core customers and the **specific** steps required for downstream commercialization
  - Teams are required to conduct 100 interviews
- Gather information essential to customer partnerships/ collaborations/ purchases before doing the science
- Identify financing vehicles before they are needed (helping to avoid the “Valley of Death”)

## **I-Corps™ is based on a curriculum called Lean LaunchPad**

- Developed by Steve Blank as a graduate course at Stanford
- Brings together customer development, agile development, business model generation, and pivots



### **Steve Blank**

- Serial entrepreneur
- 21 years / 8 startups
- 13 years @ Berkeley, Columbia, Stanford, & UCSF

Technology commercialization efforts have two components

## **1. The science/technology**

## **2. The business model**

- **Commercialization efforts often focus on #1**
- **Successful efforts require the team to do both**

Innovation Corps (I-Corps™) program is focused on developing the business model

- 7 I-Corps™ Nodes
- > 50 I-Corps™ Sites
- I-Corps™ at NIH instructors come from nodes
  - Trained with I-Corps curriculum

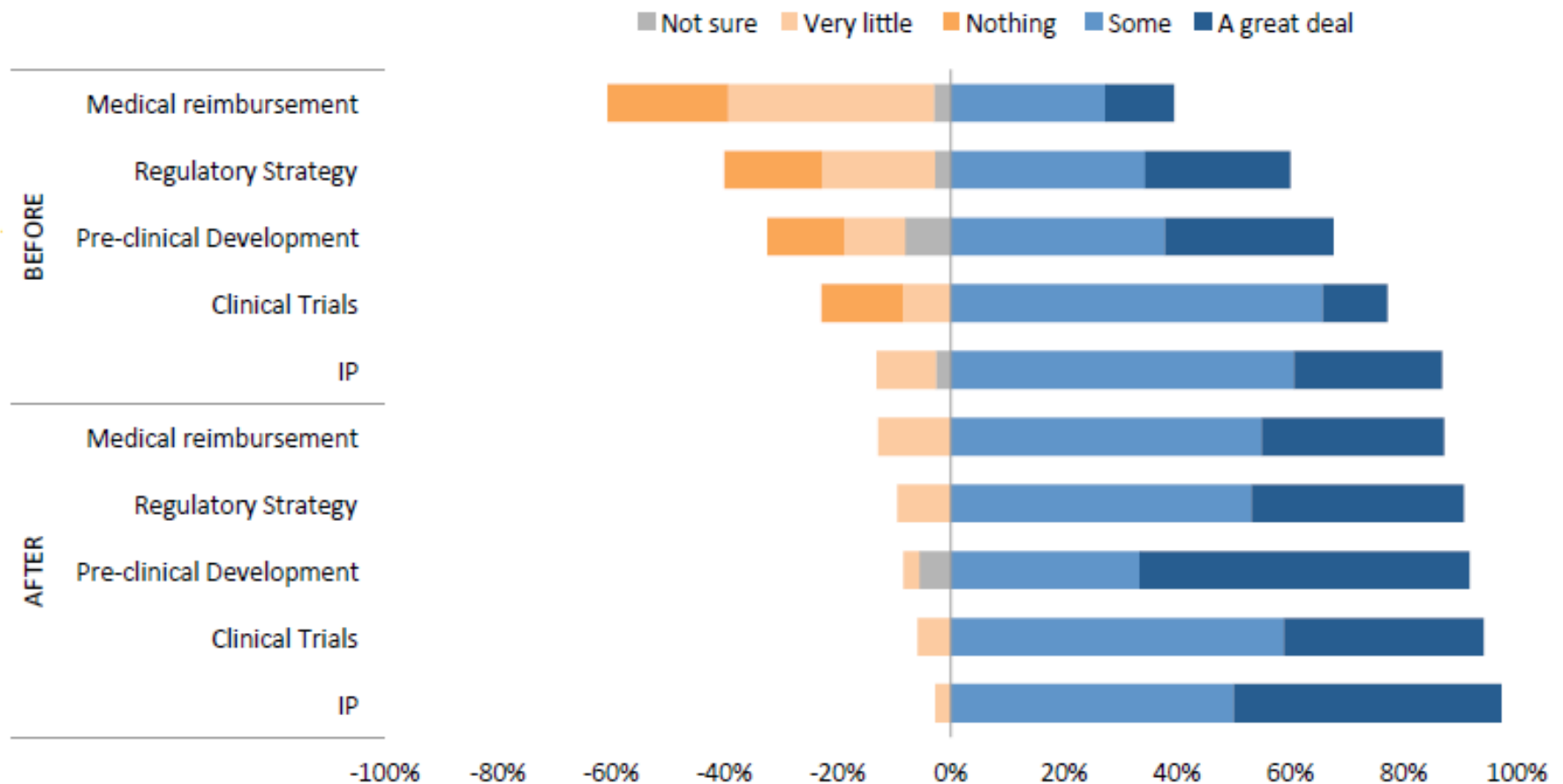




# Life Science Commercialization Knowledge

Spring 2016 Cohort

## Knowledge of areas of Commercialization & Life Sciences



- **Funding Mechanisms: Contracts v Grants**
- **Tips on Applying**
  - Deciding to Apply
  - Building the Application
  - After you Submit the Application

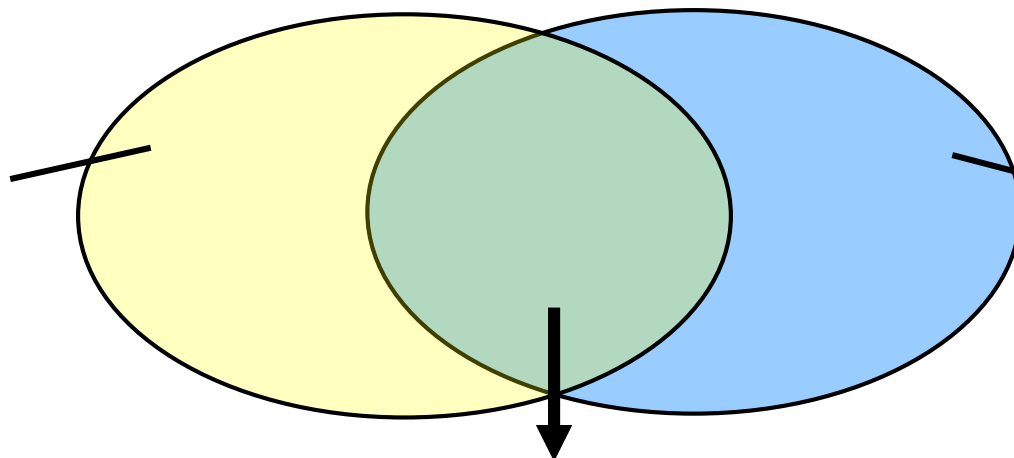
# NCI SBIR Contract Funding Opportunities

<http://sbir.cancer.gov/funding/contracts>

**Due Date Oct 21, 2016**

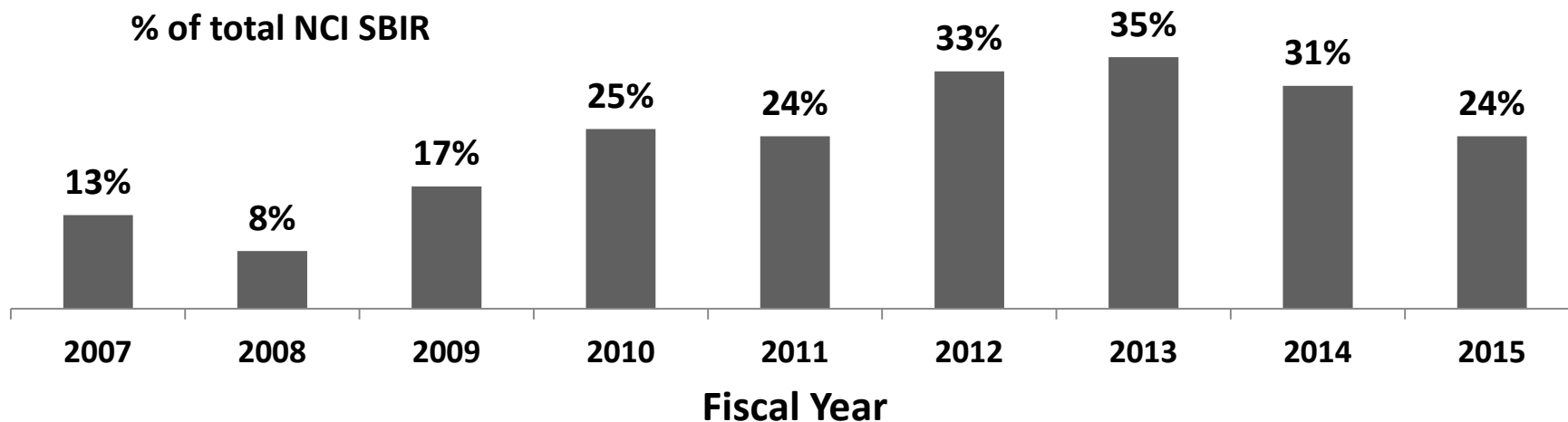


NCI scientific & technology priorities



Areas of interest to the commercial sector, based on market opportunity

Contract topics in NCI priority areas with strong potential for commercial success



# SBIR Contracts vs. Grants



	SBIR Grants	SBIR Contracts
<b><i>Scope of the proposal</i></b>	Investigator-defined within the mission of NIH	<b>Defined (narrowly) by the NIH</b>
<b><i>Questions during solicitation period?</i></b>	May speak with any Program Officer	<b><u>MUST</u></b> contact the contracting officer [ncioasbir@mail.nih.gov]
<b><i>Receipt Dates</i></b>	3 times/year for Omnibus	Only ONCE per year
<b><i>Peer Review Locus</i></b>	NIH Center for Scientific Review (CSR)	<b>NCI DEA (target 50% business reviewers)</b>
<b><i>Basis for Award</i></b>	Peer review score/ Program assessment	Peer review score/negotiation of technical deliverables, budget
<b><i>Reporting</i></b>	One final report (Phase I); Annual reports (Phase II)	Kickoff presentation, quarterly progress reports, final report, commercialization plan
<b><i>Set-aside funds for particular areas?</i></b>	No	Yes
<b><i>Program Staff Involvement</i></b>	Low	High

- **PHS-2017-1 HHS Small Business Innovation Research (SBIR) Program Contract Solicitation**
- **ONE application receipt date per year:**
  - Published August 1, 2016

**Receipt Date: October 21, 2016, 5:00 PM EDT**

- **RFP can be found at:**
  - <https://sbir.nih.gov/sites/default/files/PHS2017-1.pdf>
- **More info about NCI's topic areas:**
  - <http://sbir.cancer.gov/funding/contracts/>



# NCI Contract Topics for FY2017



- **NIH/NCI 355**: Cell and Animal-Based Models to Advance Cancer Health Disparity Research
- **NIH/NCI 356**: Tools and Technologies for Monitoring RNA
- **NIH/NCI 357**: Innovative Tools for Interrogating Tumor Microenvironment Dynamics
- **NIH/NCI 358**: Modulating the Microbiome to Improve Therapeutic Efficacy of Cancer Therapeutics
- **NIH/NCI 359**: Technologies for Differential Isolation of Exosomes and Oncosomes
- **NIH/NCI 360**: Manufacturing Innovation for the Production of Cell-Based Cancer Immunotherapies
- **NIH/NCI 361**: Highly Innovative Tools for Quantifying Redox Effector Dynamics in Cancer
- **NIH/NCI 362**: Informatics Tools to Measure Cancer Care Coordination
- **NIH/NCI 363**: Connecting Cancer Caregivers to Care Teams: Digital Platforms to Support Informal Cancer Caregiving
- **NIH/NCI 364**: Methods and Software for Integration of Cancer Metabolomic Data with Other –Omic and Imaging Data
- **NIH/NCI 365**: Imaging Informatics Tools and Resources for Clinical Cancer Research
- **NIH/NCI 366**: Clonogenic High-Throughput Assay for Screening Anti-Cancer Agents and Radiation Modulators
- **NIH/NCI 367**: Predictive Biomarkers to Improve Radiation Treatment
- **NIH/NCI 368**: Molecularly Targeted Radiation Therapy for Cancer Treatment
- **NIH/NCI 369**: Development of Pediatric Cancer Drug Delivery Devices

<http://sbir.cancer.gov/funding/contracts>

**Budget:** Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

**Number of Anticipated Awards:** 2-3

*Fast-Track proposals accepted. Direct-to-Phase II proposals accepted.*

**Goal:** Develop new, commercially available models relevant to diverse racial/ethnic populations including American Indians, Alaska Natives, Asians, African Americans, Pacific Islanders, and Hispanic/Latinos. Solicited models include patient-derived cell lines, patient-derived xenograft (PDX) mouse models, and 3D human tissue model culture systems established from racially/ethnically diverse patient populations.

**Phase I Activities & Deliverables Include:**

- Establish an experimental model derived from a racial/ethnic minority population and/or relevant to CHD research.
- Establish a stable cell line from human tumor cells and passage the cells in culture to determine viability and experimental relevance.
- Establish a serially transplantable, phenotypically stable, human cancer xenograft model in immunocompromised mice.
- Establish a 3D culture that mimics the tumor microenvironment. Note that all proposed model systems must be using established technologies with previously demonstrated reproducibility in pre-clinical or chemo-sensitivity assays.

**Budget:** Phase I \$250,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 3-5

*Fast-Track proposals **not** accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Generate tools, technologies, and products for monitoring covalently modified eukaryotic RNA, including messenger RNA and regulatory RNA. In the long term, these tools and products will allow the investigation of how altered RNA modifications contribute to the initiation and progression of cancer and potentially identify a new class of cancer biomarkers.

### **Phase I Activities & Deliverables Include:**

- Identify and justify development of a tool or technology for monitoring a specific RNA modification or set of RNA modifications.
- Develop and characterize the tool or technology for monitoring the specific RNA Modification(s).
- Develop an assay or system for testing and benchmarking the specificity and sensitivity of the tool or technology and comparing the tool or technology to existing approaches if applicable.
- Provide a proof-of-concept SOP for the tool or technology.

**Budget:** Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

**Number of Anticipated Awards:** 3-5

*Fast-Track proposals accepted. Direct-to-Phase II proposals accepted.*

**Goal:** Develop non-invasive, in vivo platforms that can: image, assess or interrogate TME dynamics over time for tumor diagnosis and/or treatment prediction/response.

**Phase I Activities & Deliverables Include:**

- Identification and validation of marker(s) for TME
- Prepare, select and demonstrate TME-targeting probes/sensors based on target specificity and minimal toxicity in vitro
- Optimize detection scheme to demonstrate in vitro signal specificity and correlate signals to molecular target concentrations measured using conventional assays
- Determine optimal dose and detection window through proof-of-concept small animal studies with evidence of systemic stability and minimal toxicity
- Establish calibration curves correlating in vivo signal changes to concentration of molecular targets measured via conventional biological assays.
- Demonstrate robust signal changes in response to in vivo perturbation
- Benchmark experiments against currently state-of-the-art methodologies.
- Present Phase I results and development to NCI staff

**Budget:** Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

**Number of Anticipated Awards:** 2-4

*Fast-Track proposals **not** accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Develop effective adjuvant strategies that specifically target critical microbial activities or populations that affect drug efficacy and/or tolerability.

**Phase I Activities & Deliverables Include:**

- Define and characterize a host/microbe interaction that affects therapeutic efficacy, demonstrated through appropriate in vitro and in vivo experiments.
- Develop targeted microbiota regulated/directed intervention strategies designed to improve, either alone or in combination, patient outcomes for new or current therapeutic agents
- Test and refine therapeutic approaches in order to identify lead candidates or agent to develop further in Phase II studies
- Offeror should determine and justify the assays and endpoints that will be used to evaluate the success of their approach.
- Submit a statement to NCI that specifies the metrics and criteria used to evaluate the success of the approach being developed, and justification for these metrics and criteria from a commercial and scientific perspective.

**Budget:** Phase I \$300,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 2-3

*Fast-Track proposals **not** accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Accelerate the use of exosomes from body fluids for cancer research and clinical care, and Develop technology for differential isolation of tissue-specific exosomes and oncosomes in serial collections of archived body fluids to enable assessment of cancer initiation, progression, risk, aggressiveness, prognosis and/or treatment outcomes.

## **Phase I Activities & Deliverables Include:**

- Develop a technology for differential isolation of exosomes and oncosomes, which originated in a specific tissue, from body fluid(s) collected from cancer patients.
- Demonstrate that the technology can obtain distinct preparations of exosomes and oncosomes from the routinely collected fresh/archived body fluids, and yields sufficient quantity for downstream analysis.
- Demonstrate that the reproducibility is >90% and yield is >70%
- Demonstrate collection of >75% intact and undamaged exosomes/oncosomes is using physicochemical methods.
- Deliver to NCI the SOPs for exosome/oncosome isolation, and the data from physicochemical characterization that demonstrates the quality



**Budget:** Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

**Number of Anticipated Awards:** 2-4

*Fast-Track proposals accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Facilitate the development of innovative methods and technologies capable of improving and modernizing product manufacturing processes for cell-based cancer immunotherapies.

**Phase I Activities & Deliverables Include:**

- Develop a device/technology/process to support commercially-relevant manufacturing advancements or improvements for the production of a specific class of cell-based cancer immunotherapies
- Provide proof of collaboration or partnership with an entity that is developing a representative cell-based therapeutic agent OR otherwise demonstrate access to a representative cell-based therapeutic agent through other means that can be used for validation of the device/technology/process
- Demonstrate pilot-scale beta-testing of the production process to demonstrate reproducible performance within appropriate specifications for identity, purity, potency, and/or other relevant metric for the chosen cell-based immunotherapy product

**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 2-4

*Fast-Track proposals **not** accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Develop quantitative tools to measure redox dynamics in biological systems. Ideally, probes or biosensor tools should be minimally invasive as to not significantly perturb the system. The technical approach should: (1) allow for in vivo measurements of redox effector spatiotemporal dynamics; and-or (2) be useable in high throughput systems.

## **Phase I Activities & Deliverables Include:**

- Identify and justify development of a sensing tool or probe for specific redox effector species from both a cancer biology and commercial perspective.
- Develop and characterize a redox probe, biosensor or detection platform. Offerors shall specify quantitative milestones that can be used to evaluate the success of the technology being developed, and justify these milestones from the viewpoint of both scientific utility and commercial value.
- Develop an assay or system that demonstrates proof-of-concept testing and benchmarking of specificity and sensitivity parameters of the agent or system for a range of redox effector species.

**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 2-3

*Fast-Track proposals accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Create scalable health IT-based informatics tools that measure care coordination in order to assess and improve quality of care and patient outcomes, assist the ongoing healthcare delivery system transformation and improve research efficiency.

**Phase I Activities & Deliverables Include:**

- Develop a prototype platform to generate at least 5 cancer-relevant care coordination measures from EHRs and other relevant, IT platforms at one cancer care delivery site and to display them in the right format to the right user at the right time.
- Develop a prototype platform to assess clinical team composition; workflows and team interactions with health IT; flow of relevant data across diverse delivery sites; extent of patient engagement; type of health IT implementation, and organizational structure and policies relevant to the informatics tool development and implementation at one cancer care delivery site.
- Provide a report detailing plans for implementation of technical assistance and delivery of software, platform, and measures developed.

**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 2-3

*Fast-Track proposals accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Develop software, database systems and mobile application tools to support cancer caregivers and connect them with their patients' care teams.

**Phase I Activities & Deliverables Include:**

- Establish a project team with expertise in the areas of software development, patient-centered design, health communication, oncology, oncology nursing, palliative care, family medicine behavioral science, health services, and computer programming. Note that team members may have dual expertise
- Perform an environmental scan of available and relevant software systems designed to support cancer patients and caregivers to identify major gaps
- Conduct a small number of key informant interviews with cancer patients and caregivers to further refine and prioritize areas of unmet needs
- A dashboard/database that would communicate to caregivers, patients, and providers about community resources
- Develop a functional prototype of the software system

**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 2-3

*Fast-Track proposals accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Develop new and innovative bioinformatic methods to integrate metabolite data with and other –omics and/or cancer imaging data and ultimately design scalable software tool(s) that apply these methods to automate the integration of the data.

## **Phase I Activities & Deliverables Include:**

- Develop bioinformatic methods for identified metabolite data integration with other –omics and/or cancer imaging data for at least one analytical technology used in metabolomics and at least one analytical technology used in in genomics, proteomics, epigenomics, transcriptomics, or cancer imaging. Datasets with cancer outcomes must be used.
- Develop data formats that support the import and export of individual datasets and “combined” datasets, store structured data from different sources of metabolite and other –omics and/or cancer imaging data, and are readily used for data integration and QC protocols.
- Finalize data formats and structure, data collection, transport and importation methods for targeted Phase I data inputs.

**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 2-3

*Fast-Track proposals accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Develop and implement solutions for sustained support for the advanced development, evolution, and broad adoption of cancer imaging informatics tools and resources.

**Phase I Activities & Deliverables Include:**

- Design specifications for enhancing image informatics tools and resources to support required usability, data and tools interoperability, patient data protection, as well as other features required for supporting phase II commercialization,
- Clear documentation of the tools and resources, and
- An early phase product prototype and detailed project plan for phase II implementation, as well as a demonstration of the prototype to NCI (using funds set aside for this purpose).



**Budget:** Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

**Number of Anticipated Awards:** 3-5

*Fast-Track proposals **not** accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:**

- (i) Promote stronger academic industry partnerships in radiobiology to develop clonogenic survival-based HTS systems
- (ii) Exploit recent advances in the technical maturity of HTS technologies and combine them with advances in clonogenic assays
- (iii) Encourage small businesses to specifically develop HTS systems for screening potential anti-cancer agents based on a clonogenic endpoint
- (iv) Integrate relevant technologies.

**Phase I Activities & Deliverables Include:**

- Delivery of a prototype system with validated SOPs that are translatable to other laboratories.
- Defined cell line panels that have been shown to be appropriate for use with the system and the clonogenic endpoint. Validation of representative “hits” using conventional clonogenic assay.
- Licensing of individual components for use in the system as needed.

**Budget:** Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

**Number of Anticipated Awards:** 2-3

*Fast-Track proposals accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Develop a simple cost effective test that can be used by clinicians to personalize radiation/chemoradiotherapy treatment regimens.

## **Phase I Activities & Deliverables Include:**

- Discovery and early development
  - Demonstrate biomarker prevalence and utility
  - Develop a working qualitative test correlating the presence or absence of the biomarker(s) with potential outcome or a quantitative assay to assess radiation sensitivity
  - Demonstrate feasibility
- Preclinical development and technical validity
  - Provide assay characteristics
  - Illustrate the performance of the biomarker(s) with receiver operating characteristic (ROC) data
  - Demonstrate suitability of the test for use in the clinic, including kinetics of biomarker, if transient.

**Budget:** Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

**Number of Anticipated Awards:** 2-3

*Fast-Track proposals accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:**

- Short-term goal - to perform feasibility studies for development and use of possible radiotherapeutics for the treatment of cancer.
- Long-term goal - to enable a small business to bring a fully developed TRT compound or TRT-supporting technology to the clinic and eventually to the market.

**Phase I Activities & Deliverables Include:**

- Proof-of-concept of the conjugation or attachment of the radioisotope to the antibody or other targeting moiety.
- Radiation dosimetry studies in an appropriate small animal model
- Proof-of-concept small animal studies demonstrating an improved therapeutic efficacy and improved therapeutic index, assessment of toxicity to normal tissues, and pharmacokinetic/pharmacodynamic studies utilizing an appropriate animal model.

**Budget:** Phase I \$300,000 for 9 months; Phase II \$2M for 2 years

**Number of Anticipated Awards:** 2-4

*Fast-Track proposals **not** accepted. Direct-to-Phase II proposals **not** accepted.*

**Goal:** Develop technologies to aid the administration of cancer therapies to pediatric patients, taking into account pediatric specific issues which include but are not limited to: dosage limitations, size restraints, comfort level and mobility.

**Phase I Activities & Deliverables Include:**

- Select cancer type(s), site(s) and cancer drugs for the development of delivery device with adequate justification
- Design and develop a prototype of a drug delivery device that is
- Suitable for the anatomical restrictions of pediatric patients.
- Suitable for the dosage limitations of pediatric patients.
- Demonstrate preliminary proof-of-concept of the device in a suitable animal model.
- Develop the required specifications necessary to make the device clinic ready.
- Demonstrate understanding of the requirements to file a regulatory application for the device

# What Does It Take to Get Funded?

## *Tips on Applying*



- **SBIR/STTR applicants are smart, highly skilled, accomplished, and hail from top institutions**
- **NIH receives many strong SBIR/STTR proposals**
- **SBIR/STTR awards are highly competitive**
  - **Funding success rate around 10-15%**
  - **Resubmissions are very common**
- **You must prepare a strong application!**



## Deciding to Apply



# When is an SBIR/STTR appropriate?



- Innovative solution to significant **unmet clinical need**
- Solution has **significant commercial potential**
- Leverages company/founder expertise
- Seeking funding to produce **feasibility data (Phase 1)**
- Seeking funding for **development (Phase 2)**
- Start-up company, too early for private investment
- Established SBC, seeking funding to pursue a new project (and your Board supports an SBIR application)


- **Chasing NIH funding solicitations – “why not?”**
- **Need cash urgently**
  - Time from application to award is 8-12 months; SBIR/STTR funding should be part of a larger financing strategy
- **“Me too” product matching competitor’s capabilities**
- **Incremental innovation: no change to clinical paradigm**
- **Basic research still required to demonstrate commercial and clinical feasibility**
- **Trying to bridge the gap when you have lost your R01**

- **Consider your company's strengths and how to exploit them**
- **Consider your company's weaknesses and how to address them**
- **Contact an appropriate NIH Program Director in advance (at least 1 month before due date!), to discuss your specific aims and receive feedback**
- **Review similar, currently-funded NIH projects**
  - NIH Project RePORTER

# Search Previous Awards



## http://projectreporter.nih.gov

**Research Portfolio Online Reporting Tools  
(RePORT)**

Search


HOME | ABOUT RePORT | FAQs | GLOSSARY | CONTACT US

QUICK LINKS | RESEARCH | ORGANIZATIONS | WORKFORCE | FUNDING | REPORTS | LINKS & DATA

Note: RePORTER will be temporarily unavailable for system updates from 10 p.m. (ET) Saturday, June 29 until 7 a.m. (ET) Sunday, June 30. We apologize for any inconvenience.

Home > RePORTER > Query Form

My RePORTER Login | Register System Health: GREEN

**NIH RePORTER**  
Version: 5.7.0  
06/13/2013 Release Note: New enhancements now available.  
View [Release Notes](#) for more information.

About RePORTER DATA | FAQ | ExPORTER | RePORTER Manual | RSS of Newly Added Projects

QUERY NEW | OLD QUERY | BROWSE NIH BETA

Old query form available until July 11

SUBMIT QUERY | CLEAR QUERY

Fiscal Year (FY): ? Active Projects SELECT  
Current FY is 2013

RESEARCHER AND ORGANIZATION

Principal Investigator (PI) / Project Leader: ?    
(Last Name, First Name) Use '%' for wildcard  
[Enter several PI/Project Leader names](#)

Organization: ?  LOOKUP  
Please enter at least 3 characters to use Lookup.  
☒ Contains ☐ Begins with ☐ Exact

Department: ? SELECT

Organization Type: ? SELECT

City: ?   
Use '%' for wildcard

State: ? SELECT SELECT

Country: ? SELECT SELECT


Congressional District: ? SELECT SELECT

DUNS Number: ?


# Search Previous Awards

<http://projectreporter.nih.gov>

**TEXT SEARCH**

Text Search (Logic):  

☒ And  
☐ Or  
☐ Advanced

Search in   
☒ Projects  
☐ Publications  
☐ Projects & Publications

Limit Project search to  
☐ Project Title  
☐ Project Terms  
☐ Project Abstracts

Limit Publication search to  
Start Year   
End Year

**PROJECT DETAILS**

Project Number:   
Format: 5R01CA012345-04  
Use '%' for wildcard, e.g. %R21%  
[Enter multiple project numbers/application IDs](#)


OR


1  R01  CA  811099  01  A1S1

Project Start Date: >=   
Format: mm/dd/yyyy

Project End Date: <=   
Format: mm/dd/yyyy

Award Notice Date: >   
Format: mm/dd/yyyy


Agency/Institute/Center:     
☒ Admin ☐ Funding

NIH Spending Category:  

Funding Mechanism:

☒ Check/Uncheck All

- ☒ Research Project Grants
  - ☐ Non-SBIR/STTR
  - ☒ **SBIR/STTR**
  - ☐ Research Centers
- ☐ Other Research-Related
- ☐ Training, Individual
- ☐ Training, Institutional
- ☐ Construction Grants
- ☒ R and D Contracts
  - ☐ Non-SBIR/STTR Contracts
  - ☒ **SBIR/STTR Contracts**
  - ☐ Interagency Agreements
  - ☐ Intramural Research

Award Type:  



# Building the Application



- **Strong proposals take time to develop!**
- **Carefully read the funding solicitation, and allow time to address all of the key requirements**
  - Assemble a strong scientific team
  - Gain access to equipment and other resources
  - Obtain letters of support from collaborators
- **Complete the necessary administrative registrations**
  - Start this at least 2 months before deadline!
  - <http://sbir.nih.gov> > see info on *Electronic Submission*
  - [See SF424 application guide](#) (grants.gov, eRA Commons)

## New PDF guide

FORMS VERSION D SERIES  
UPDATED MARCH 25, 2016



### **SBIR/STTR INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES**

SF424 (R&R) APPLICATION PACKAGES

## New web-based guide

[Home](#) [Download PDF](#)

GENERAL APPLICATION GUIDE FOR NIH AND OTHER PHS AGENCIES

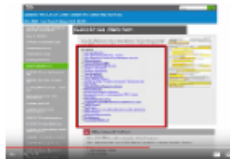
SF424 (R&R) - Forms Version D - Updated March 25, 2016

G.100 How to use the Application Instructions

[G.110 Application Process](#)  
[G.120 Significant Changes](#)  
[G.130 Program Overview](#)  
[G.200 SF 424 \(R&R\) Forms](#)  
[G.210 PHS 398 Cover Page Supplement Form](#)  
[G.220 R&R Other Project Information Form](#)  
[G.230 Project Performance Site Locations Form](#)  
[G.240 Senior/Key Person Profile \(Expanded\) Form](#)  
[G.300 R&R Budget Form](#)  
[G.310 R&R Subaward Budget Attachment\(s\) Form](#)  
[G.320 PHS 398 Modular Budget Form](#)

### G.100 - How to Use the Application Instructions

[Tour the new Application Guide!](#)



- Become familiar with the application submission process.
  - Understanding the information in the Application Process section of this guide, including required registrations, is critical to successfully submitting your application.
- Use these instructions in conjunction with your funding opportunity announcement (FOA).
  - Remember that the funding opportunity announcement instructions always supersede these application instructions.
- Pick a format.
  - **Comprehensive.** Use the general (G) instructions, available in both HTML and PDF format, to complete the application forms for any type of grant program.
  - **Program-specific.** Take advantage of the filtered PDFs to see just the instructions you need for research (R), career development (K), training (T), fellowship (F), multi-project (M) or SBIR/STTR (B) applications.
- Determine which instructions are needed.
  - Refer to [Selecting the Correct Application Instructions](#) to match the activity code of your funding opportunity to the needed instructions (e.g., the R01 activity code maps to the Research (R) instructions).
  - Consult the Program Overview section for context for program specific instructions.

## Application Submission System & Interface for Submission Tracking (ASSIST)

Earliest Start Date

Standard dates apply

Expiration Date

April 6, 2017

Due Dates for E.O. 12372

Not Applicable

### Required Application Instructions

It is critical that applicants follow the instructions in the [SF424 \(R&R\) SBIR/STTR Application Guide](#) except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](#)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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 traditional 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](#)

Problems downloading ASSIST should be directed to the [eRA Service Desk](#).

Problems downloading forms should be directed to [Grants.gov Customer Support](#).

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[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

## Key #2 – Take Time to Refine the Vision



- **Start informal discussions to clarify the product vision**
  - Technical experts, potential customers, investors, commercialization partners, and other stakeholders
- **Seek help from others with experience and insights**
  - Current/prior SBIR grantees
  - Academic collaborators with grant writing experience
  - Professional grant writers\*
  - **Engage with SBIR program staff early in the process to provide a summary of specific aims and request feedback**
- **Carefully consider the study design**
  - Identify strategies to mitigate risk
  - Present alternative approaches if problems are encountered



- **Select a Principal Investigator (PI) with the right expertise**
- **For multidisciplinary projects, consider a multi-PI team**
  - Are multiple PIs needed to cover the necessary expertise?
  - Must appoint Contact PI (SBIR, > 50% of time w/ business)
- **Partner to fill the gaps**
  - Academic collaborations
  - Consultants and CROs
  - Other companies/strategic partners
  - Business executives who understand product development

- **Specific Aims (1 page):** *Grab and Secure Positive Attention*
  - Focal point of the application
  - Highlight the technology's major strengths
  - Describe goals of the application (be specific)
  - Include quantitative performance milestones
  - Describe the unmet need that you are attempting to address
- **Research Strategy**
  - Provide background information
  - Provide detailed technical plan to achieve the Specific Aims
  - Propose a project scope within the budget and time constraints
  - Preliminary data not required (Ph I), but needed to be competitive
  - Describe potential pitfalls and alternative angles of attack

# Key #4 – Draft a Clear Application (cont'd)



- **Other application components**
  - **Letters of support**
    - **Necessary from consultants and collaborators**
    - **Powerful endorsements when obtained from clinicians, other end-users, and potential investors/partners**
  - Phase II Commercialization Plan (12 pages)
  - Cover Letter – Not seen by reviewers
    - Used to **request and justify a specific study section**
    - Used to **request dual assignment to multiple NIH ICs**
      - **New in Forms-D: PHS Assignment Request Form complements the cover letter**
  - Bio-sketches for all senior and key personnel (< 4 pages each)
  - Budgets for each project period & for each subcontract
  - Detailed descriptions of facilities and equipment
  - Human subject research section (if applicable)
  - Vertebrate animals section (if applicable)

## **BEFORE YOU SUBMIT:**

- **Read your application as if you were a reviewer**
  - What are the weaknesses?
  - Point out potential pitfalls (don't try to hide them); and suggest strategies to address potential problems
- **Ask your collaborators to critically review the application**
- **Solicit feedback from independent, technically-trained readers**
  - Do they understand the proposal?
  - Are they excited about the idea, the potential impact, and the experimental approach?

# Know NIH Review Criteria

## Significance

- Does the product address an important **problem**, and have commercial potential? Is there a market pull for the proposed product?

## Approach

- Are **design and methods** well-developed and appropriate? Are problem areas addressed? Are potential pitfalls and alternative approaches provided?

## Innovation

- How novel is the **technology/product** and the **approaches** proposed to test its feasibility?

## Investigator

- Are the investigators, collaborators and consultants appropriately trained and **capable** of completing all project tasks?

## Environment

- Does the **scientific environment** contribute to the probability of success? **Facilities**? Independence?

## Commercialization

- Is the company's **business strategy** one that has a high potential for success?

# After You Submit the Application





# What if you are not funded?

- **Rejection is painful, BUT...**
- **Feedback provides a roadmap for next steps**
  - Carefully review the Summary Statement (written critiques)
  - Use reviewer comments to improve your application
  - Discuss Summary Statement with your NIH Program Director
- **Revise and resubmit the application**
  - Introduction Page: Response to reviewer critiques
  - Be constructive not defensive
- **Learn more about SBIR/STTR grants**
  - Talk to successful applicants
  - Understand review process and dynamics - <http://csr.nih.gov>

- **Reviewers do not believe you are working on significant problem**
  - Carefully consider reviewer comments in the context of their view of current clinical practice (or relevant sector)
  - Address reviewer comments in an evidence-based fashion
  - Be specific and quantitative when providing data to support your claims
  - Obtain additional letters of support from stakeholders who can confirm the magnitude of the problem AND the potential impact of your solution

- **Reviewers did not understand your proposal**
  - **Possible Reason:** Proposal is not clearly written
    - **Solution:** Improve your presentation
  - **Possible Reason:** Not enough data, or vague descriptions of the technology (e.g., chemical structure for lead compound)
    - **Solution:** Don't rely solely on publications. Include any relevant information that doesn't threaten your IP position
  - **Possible Reason:** Proposal was reviewed by the wrong study section
    - **Solution:** Discuss study section assignment with your NIH Program Director. Can you identify a more appropriate study section?

- **Reviewers say the proposal is ‘not innovative’**
  - **Possible Reason:** Technology is not clearly differentiated
    - **Solution:** Describe how the technology is positioned relative to available alternatives; how are you benchmarking your solution against other competing technologies?
  - **Possible Reason:** Your solution combines existing technologies or approaches that (by themselves) are not innovative
    - **Solution:** Emphasize the novelty of how your combined approach is novel – be specific about the value proposition!

- **Reviewers believe the team is not qualified**
  - Strengthen your team by adding collaborators and consultants
  - If the PI has specific gaps in his/her or expertise, consider assembling a multi-PI team
  - Ensure that all collaborators have reviewed the proposal to help identify gaps
  - Consider including a management plan/strategy that describes who is completing which aspects of the work, and why they are qualified to complete that work

- **Total budget and duration of project period should be determined by needs of the project**
- **Must adhere to the statutory requirements and other NIH program guidelines stipulated in the funding announcement**
- **Eligibility:**
  - SBIR Phase I (  $\geq 66\%$  of the work at company)
  - STTR Phase I (40% at the company, 30% at research inst)
  - Other work may be outsourced to a subcontractor(s)
  - Fee-for-service activities may count as direct costs
    - Intellectual work and analysis must be done by the company
    - Indirect costs are a defining characteristic of subawards
  - Discuss with NIH Program Director and/or grants specialist



- **Contract proposal or grant application?**
- **Phase I versus Fast-Track or Direct to Phase II?**
  - Things to consider:
  - Stage of development (early or late, e.g., clinical trials)
  - Companies that have already been awarded grants on a particular technology, familiar with common concerns
  - Companies that have demonstrated track record of commercialization

- **Environment, facilities and resources**
- **NOT necessary to have these secured at the time of application, but must be in place at the time of award**
- **Criterion score includes an evaluation of the facilities, so these components must be described in the application**
  - Be detailed and specific
  - Reiterate how personnel and resources combine to provide the right pieces to complete the aims
  - Utilize core facilities and/or reputable CROs and/or other outside organizations as appropriate

# THANK YOU!



<http://sbir.cancer.gov>

[@NCIsbir](#)



## 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

### [Are you in Boston, MA?](#)

July 26, 2016

Join us @ JLABS in Cambridge on August 31!

### [NEW I-Corps at NIH FOA Now Available!](#)

August 30, 2016

The 2017 I-Corps at NIH FOA is now available. Next deadline=Nov 1, 2016! [\[MORE\]](#)

### [NCI SBIR is Coming to Your City!](#)

August 30, 2016

This September, we are going to IN, CA, TX, NC, MD, WA, and [\[MORE\]](#)

### [Meet with NCI SBIR at HHS SBIR/STTR](#)



[www.linkedin.com/company/nci-sbir-development-center](http://www.linkedin.com/company/nci-sbir-development-center)