

Leveraging NCI
SBIR/STTR Opportunities with
Direct to Phase II Pilot and Phase IIB Bridge Awards

March 6, 2014 12:30 – 1:45 pm EST

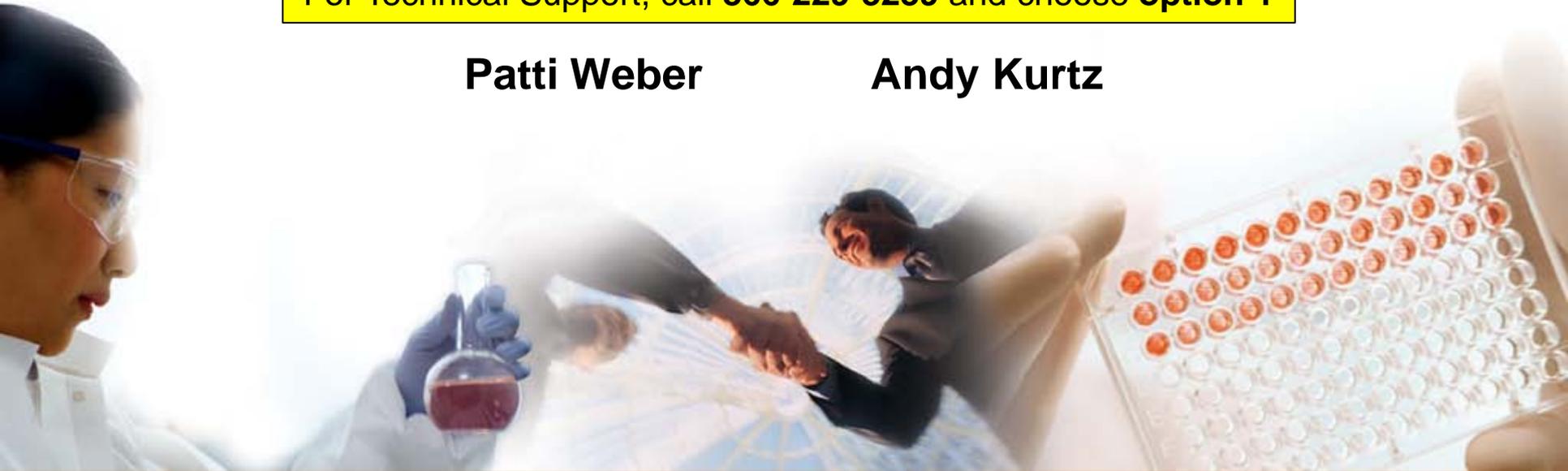
For audio, dial in: 855-244-8681

Meeting ID: 736 159 274

For Technical Support, call **866-229-3239** and choose **option 1**

Patti Weber

Andy Kurtz



Submit Your Questions

- Submit your questions any time via the Q&A box on the right-hand side of your screen.
- If you do not see the Q&A box, you can expand it by hovering over the **green bar** at the top of your screen and clicking the Q&A button.



- Please submit questions of a general nature via the Q&A Box with no proprietary information.
- Please be advised we will not answer questions specific to your project in this webinar.
- You can also send your questions to NCIsbir@mail.nih.gov
- The webinar slides, audio recording, and Q&A will be published to the website, <http://sbir.cancer.gov>
- All webinar registrants will be emailed links to access webinar slides, audio recording, and Q&A

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Patti Weber

- **Overview & Recent Updates in Eligibility**
- **The NIH SBIR/STTR Programs**
- **New Direct to Phase II Pilot Program**
- **The NCI SBIR Development Center**

Andrew Kurtz

- **Finding Funding Opportunities**
- **NCI Bridge Phase IIB Award**
- **Practical Strategies for Applying**

Q&A

Congressionally-Mandated Programs



| | Set Aside | |
|---|-------------|-------------|
| | (FY14) | (FY15) |
| <p>➤ Small Business Innovation Research (SBIR)</p> <p>Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization</p> <p><i>Federal agencies with an extramural R&D budget > \$100M</i></p> | 2.8% | 2.9% |
| <p>➤ Small Business Technology Transfer (STTR)</p> <p>Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization</p> <p><i>Federal agencies with an extramural R&D budget > \$1B</i></p> | 0.4% | 0.4% |

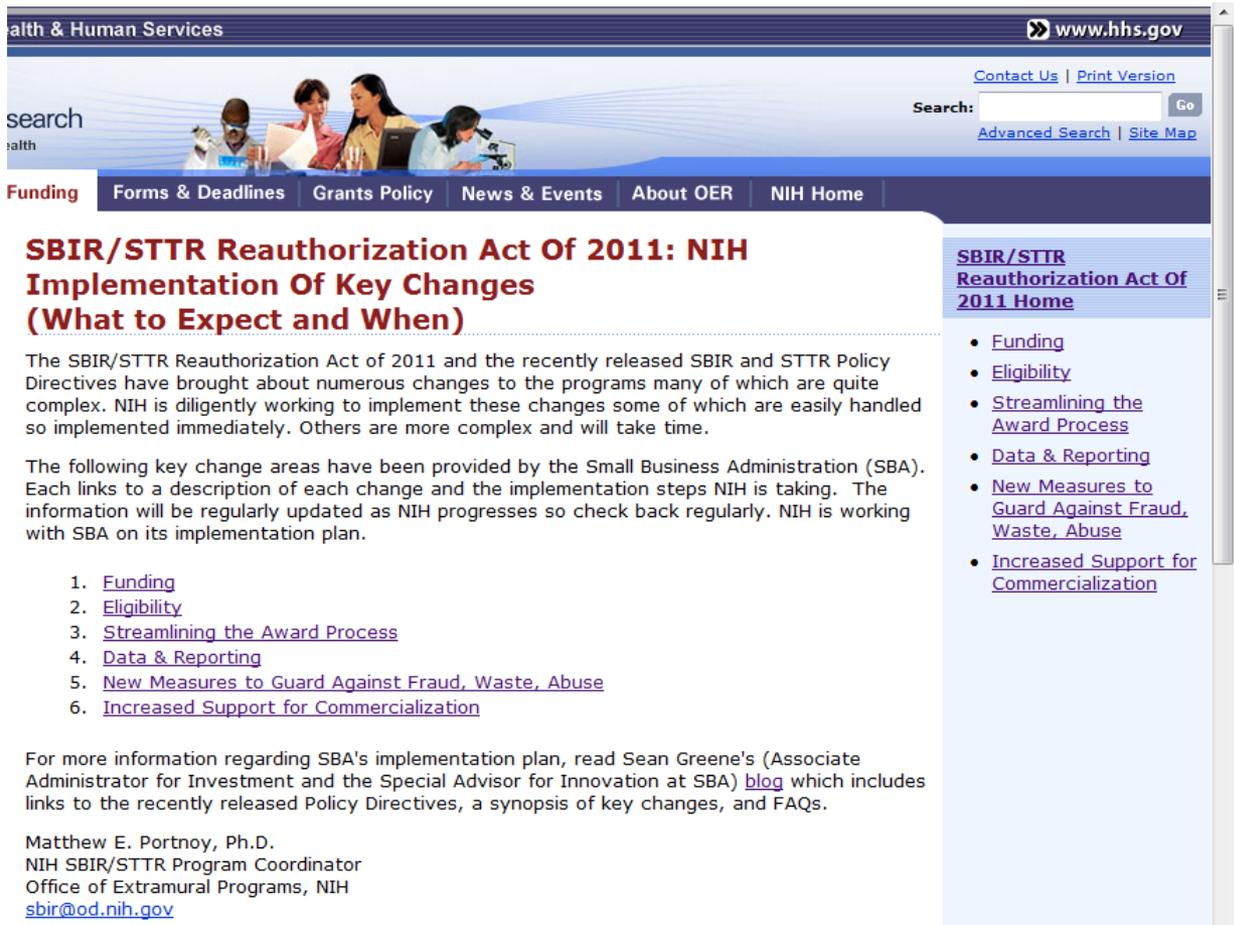
~\$700M annually at NIH
~\$115M annually at NCI

Set-aside is Increasing

| FY | SBIR Set-aside | STTR Set-aside |
|-----------------------|----------------|----------------|
| 2011 | 2.5% | 0.30% |
| 2012 | 2.6% | 0.35% |
| 2013 | 2.7% | 0.35% |
| 2014 (current) | 2.8% | 0.40% |
| 2015 | 2.9% | 0.40% |
| 2016 | 3.0% | 0.45% |
| 2017 | 3.2% | 0.45% |

- Provides seed funding for innovative technology development
- **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)

<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 for Funding, Forms & Deadlines, Grants Policy, News & Events, About OER, and NIH Home. The main content area features a large heading: "SBIR/STTR Reauthorization Act Of 2011: NIH Implementation Of Key Changes (What to Expect and When)". Below this heading, there are two paragraphs of text. The first paragraph discusses the changes brought about by the Act and the Policy Directives. The second paragraph lists key change areas provided by the SBA. A numbered list of six key change areas is provided: 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" and a list of six key change areas: Funding, Eligibility, Streamlining the Award Process, Data & Reporting, New Measures to Guard Against Fraud, Waste, Abuse, and Increased Support for Commercialization. At the bottom of the page, there is a paragraph of text providing more information regarding SBA's implementation plan, a link to Sean Greene's blog, and contact information for Matthew E. Portnoy, Ph.D., NIH SBIR/STTR Program Coordinator.

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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

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](#)

Provisions in Current Omnibus Grant Solicitations



- SBIR/STTR applicants must register at the SBA Company registry at SBIR.gov.
- VC-backed companies (VCOC, hedge fund, private equity firms) **CAN NOW** apply (**NIH SBIR only**).
- Applicants can request \$5000 in Technical Assistance, beyond award cap. If requested, cannot participate in NIH Technical Assistance Programs
 - Example: regulatory consultant

- **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.
- **Direct to Phase II Pilot Program now active**

The NIH SBIR/STTR Programs

<http://sbir.nih.gov>



Ask questions any time using the Q&A box

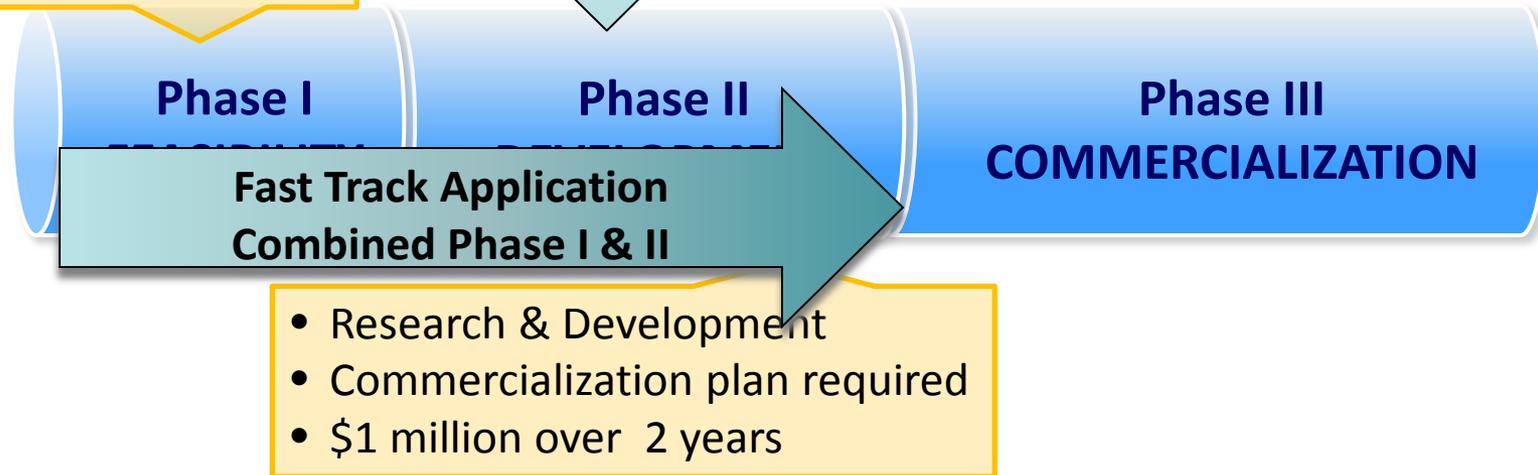
SBIR & STTR: Three-Phase Program



- Proof-of-Concept study
- \$150,000 over 6 months (SBIR) or 1 year (STTR)

Direct to Phase II
• Skip Phase I

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

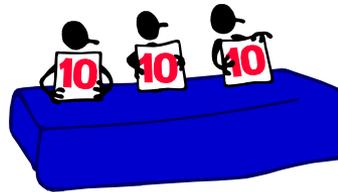
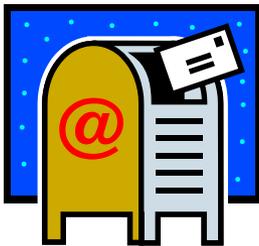


- Hard caps on award sizes: \$225,000 for Phase I; \$1.5 million for Phase II
- Certain awards may exceed these caps if covered by topic-specific waivers
- Actual funding may vary by topic

NIH Timeline for New Applications



6 - 9 months



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

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

Ask questions any time using the Q&A box

- **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?



SBIR

STTR

Principal Investigator

Primary employment **must** 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
Small business must do 67% Phase I, 50% Phase II

Requires partnering with US research institution
Small business min. 40%, Research institution min. 30%

- 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

Fast Track or Direct to Phase II: Which Program is Best for You?



Fast Track

- Promising preliminary data but still potential to propose aims that could be considered reasonable for a Ph I study, and/or good milestones to attempt to hit to make go/no go decision
- If there are reasonable/logical aims to include & fit timeline/budget as Ph I, Fast Track is likely a better option (over Direct to Phase II) because there would be more total money available

Direct to Phase II

- Have preliminary data that is equivalent to what we expect from the end of an NIH Ph I award
 - (e.g. in vivo proof of concept data for a therapeutic)
- Where it wouldn't make sense to do additional preclinical proof-of-concept
- Already in humans, doing clinical trials – probably best candidates

- 2014 SBIR Direct to Phase II Solicitation: **PAR-14-088**
- Check the funding announcement: Only NCI and NIH ICs listed are participating in Direct to Phase II Pilot
- Applies to SBIR programs only, **NOT STTR**
- Designed for SBCs that have completed Phase I-type milestones with non-SBIR funds

Direct to Phase II Pilot Program



- Standard receipt dates apply:
 - April 5 (**Monday April 7, 2014**), August 5, December 5
- Effective until 2017
- Standard SBC eligibility rules apply
- Transition Rate Benchmark for SBCs awarded >20 Ph I last 5 years
 - $$(\# \text{ Ph II awards}) / (\# \text{ Ph I awards}) \geq \mathbf{0.25}$$
- Verify your SBC Transition Rate on the Company Registry at SBIR.gov

The NCI SBIR Development Center

<http://sbir.cancer.gov>



Ask questions any time using the Q&A box

NIH = 27 Institutes & Centers

24 Participants in the SBIR/STTR Program

Office of Research Infrastructure Programs (ORIP)

The Office of the Director (OD)

National Institute on Aging (NIA)

National Institute on Alcohol Abuse & Alcoholism (NIAAA)

National Institute of Allergy & Infectious Diseases (NIAID)

National Institute of Arthritis & Musculoskeletal & Skin Diseases (NIAMS)

National Cancer Institute (NCI)

National Institute of Child Health & Human Development (NICHD)

National Institute on Deafness & Other Communication Disorders (NIDCD)

National Institute of Dental and Craniofacial Research (NIDCR)

National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)

National Institute on Drug Abuse (NIDA)

National Institute of Environmental Health Sciences (NIEHS)

National Eye Institute (NEI)

National Institute of General Medical Sciences (NIGMS)

National Heart, Lung, & Blood Institute (NHLBI)

National Human Genome Research Institute (NHGRI)

National Institute of Mental Health (NIMH)

National Institute of Neurological Disorders & Stroke (NINDS)

National Institute of Nursing Research (NINR)

National Institute on Minority Health & Health Disparities (NIMHD)

National Center for Complementary & Alternative Medicine (NCCAM)

Fogarty International Center (FIC)

National Center for Advancing Translational Sciences (NCATS)

National Library of Medicine (NLM)

National Institute of Biomedical Imaging & Bioengineering (NIBIB)

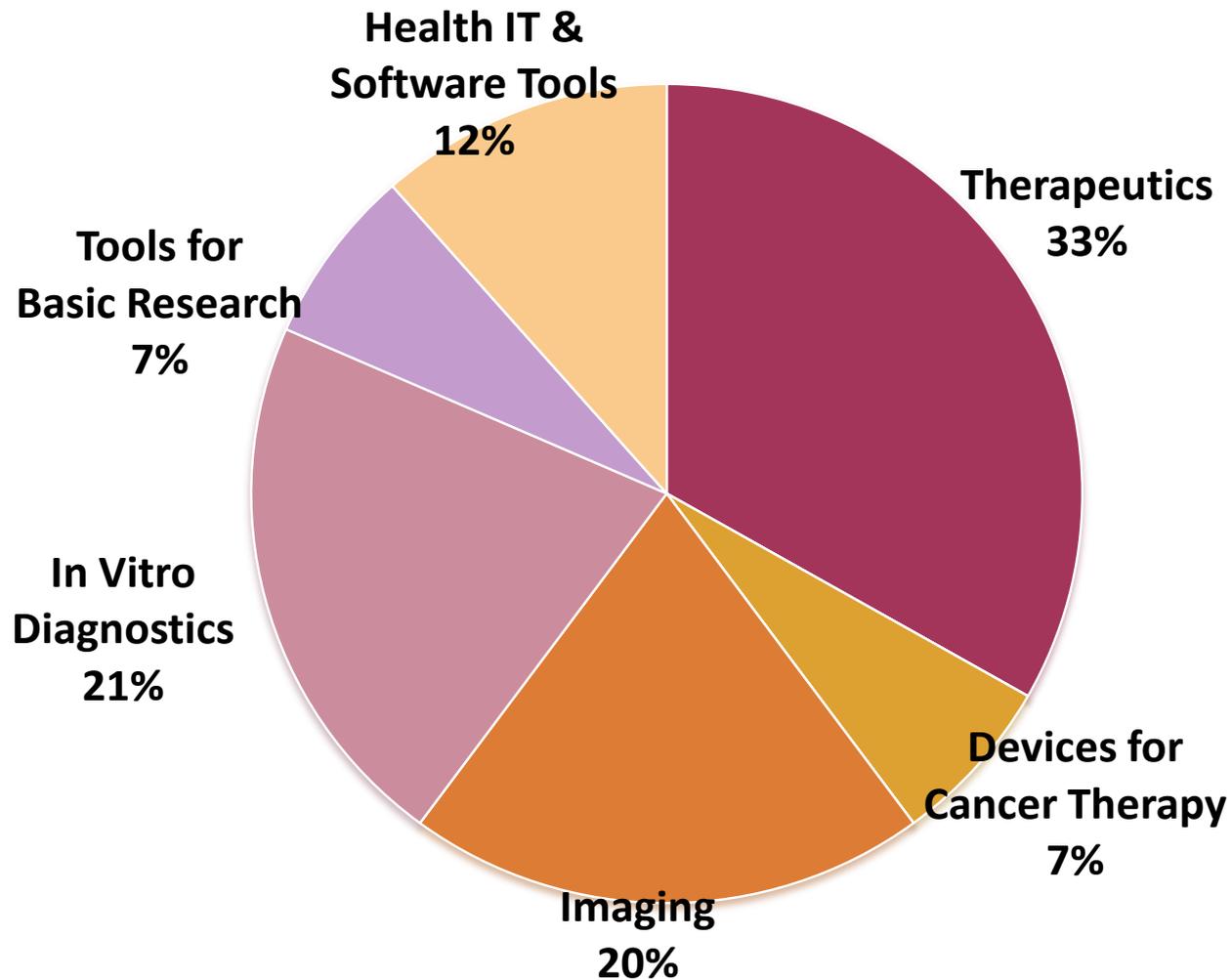
NIH Clinical Center (CC)

Center for Information Technology (CIT)

Center for Scientific Review (CSR)

← No funding authority

Pipeline of 400+ vetted projects



Ask questions any time using the Q&A box

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



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AAAS Science & Technology Policy Fellow
Policy, Outreach, Success Stories, Scientific Communications, SBIR Investor Forum, FRAC Workshop



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



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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



Jennifer Shieh, PhD
Program Director
Digital Health, Bioinformatics, Research Tools, Evaluation, SBIR Investor Forum, FRAC Workshop

Development Center staff are responsible for:

- Conducting regular outreach events to help recruit more focused, commercially-minded SBIR applicants
- Coaching applicants on developing stronger applications
- Providing oversight and active management of projects
- Mentoring and guiding companies throughout the award period
- Facilitating matchmaking with potential third-party investors and strategic partners

Submit Your Questions

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Today's Presentation

Patti Weber

- Overview & Recent Updates in Eligibility
- The NIH SBIR/STTR Programs
- New Direct-to-Phase II Pilot Program
- The NCI SBIR Development Center

Andrew Kurtz

- Finding Funding Opportunities
- NCI Bridge Phase IIB Award
- Practical Strategies for Applying

Q&A

SBIR/STTR Funding Opportunities

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



Multiple Funding Solicitations

Know the Application Deadlines



- **SBIR & STTR Omnibus Solicitations for Grant Applications**

Release: January

Receipt Dates: April 5 (**April 7, 2014**), August 5, and December 5

- **See the NIH Guide for other Program Announcements (PA's) and Requests for Application (RFA's), i.e. grants**

Release: Weekly

Receipt Dates: Various

- **NCI SBIR Bridge Phase IIB Award (RFA-CA-14-002)**

Release: February

Receipt Date: **April 21**

<http://grants.nih.gov/grants/guide>

http://sbir.cancer.gov



National Cancer Institute

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About Funding Opportunities Resource Center News & Events Success Stories

Leading small business innovation and commercialization in the fight against cancer

What are the NCI SBIR & STTR Programs?

The goal of the NCI is to eliminate the suffering and death due to cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs are NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

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 and a new spirit of collaboration with the NCI.

[\[Learn More\]](#)

Sign up for Updates

Sign up to receive updates and news about the NCI SBIR & STTR Programs and upcoming funding opportunities.

Latest Announcements

[SBIR Program FY 2011 Contract Funding Available](#)

The FY 2011 NCI solicitation for SBIR contract proposals has been issued:
[PHS 2011-1, Solicitation for SBIR Contract Proposals](#)

Receipt Date: November 8, 2010

Register Today
 2010 NCI SBIR Investor Forum
 November 9 | Stanford, CA

The NCI SBIR will host its second Investor Forum designed to connect the strongest and most promising NCI SBIR funded companies with life science

http://sbir.nih.gov



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Office of Extramural Research

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Grants & Funding

Funding Opportunities

- Funding Opportunities (RFAs, PAs) & Notices
- Unsolicited Applications (Parent Announcements)
- Research Training & Career Development
- Small Business (SBIR/STTR)
- Funding Opportunities
- Electronic Submission
- Application Submission/Review
- Policy
- Resources
- Transitioning to Phase III
- Presentations/Conferences
- Archive
- LISTSERVS
- Contract Opportunities

NIH-Wide Initiatives

- New and Early Stage Investigators
- Stem Cell Information
- NIH Common Fund
- OppNet (Behavioral & Social Sciences)

Award Data

- NIH Reports (RePORT)
- Search NIH Awards (RePORTER)

Welcome to the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs at the National Institutes of Health

News Flashes

- HHS Reissues PHS 2013-02 SBIR and STTR Omnibus Grant Solicitations Implementing Venture Capital Provision and SBA Company Registry Requirement of the SBIR/STTR Reauthorization Act of 2011
- NIH Fiscal Policy for Grant Awards - FY 2013
- NAP Program CLOSED
- NIH Office of Technology Transfer offers new exclusive license agreements for start-up companies

(Current, Archived News Flashes)

Funding Opportunities for U.S. Small Businesses

| | | |
|--|--|--|
| <p>Re-issue 2013 SBIR and STTR Omnibus Grant Solicitations of the NIH, CDC, FDA and ACF</p> | <p>Re-issue SBIR Parent Funding Opportunity Announcement (PA-13-234)</p> <p>Re-issue STTR Parent Funding Opportunity Announcement (PA-13-235)</p> <p>Program Descriptions and Research Topics (PDF - 1 MB or MS Word - 350 KB)</p> | <p>Standard Receipt Dates Remaining: Aug 5, Dec 5</p> <p>AIDS and AIDS-Related Receipt Dates: September 7, 2013, January 7, 2014</p> |
|--|--|--|

NIH SBIR/STTR Reauthorization Implementation

REPORT FRAUD, WASTE AND ABUSE

The Office of Inspector General Hotline accepts tips from all sources about potential fraud, waste, abuse and mismanagement in Department of Health & Human Services programs. The reporting individual should indicate that the fraud, waste and/or abuse concerns an SBIR/STTR grant or contract, if relevant.

Report Fraud

http://grants.nih.gov/grants/guide

Grants & Funding



Funding Opportunities

- [Funding Opportunities \(RFAs, PAs\) & Notices](#)
- [Unsolicited Applications \(Parent Announcements\)](#)
- [Research Training & Career Development](#)
- [Small Business \(SBIR/STTR\)](#)
- [Contract Opportunities](#)

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Award Data

- [NIH Reports \(RePORT\) Search NIH Awards \(RePORTER\)](#)

Funding Opportunities and Notices

The **NIH Guide for Grants and Contracts** is the official publication for NIH medical and behavioral research grant policies, guidelines and funding opportunities. [Definitions and More Information...](#)

Search the NIH Guide for:

- Active RFAs** (Requests for Applications)
 - Active PAs** (Program Announcements)
 - Recent Notices** (Released in Last 12 Months)
- [Inactive & Active Announcements \(use Advanced Search\)](#)

[Search Help](#)

With Announcement # or Keywords: (Optional)

[Advanced Search](#)

Related Resources

- [Grant Application Basics](#)
- [Grants Process Overview](#)
- [Submitting Your Application](#)
- [Applying Electronically](#)
- [Electronic Research Admin \(eRA Commons\)](#)
- [NIH Financial Operations \(w/Funding Strategies\)](#)
- [Archive of Selected Policy Notices \(1993 - Present\)](#)

 [Related Archives](#)

Browse Active Funding Opportunities

- [Requests for Applications \(RFAs\)](#)
- [Program Announcements \(PAs\)](#)

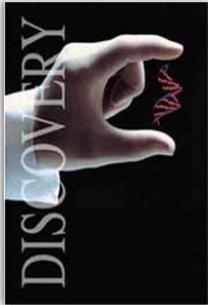
Browse Recent Policies and Guidelines

- [Notices](#) (Released in last 12 months)

NCI SBIR Phase IIB Bridge Award (RFA-CA-14-002)

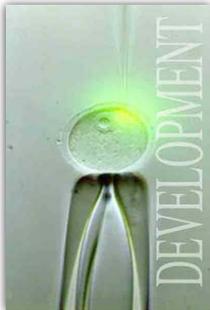
<http://sbir.cancer.gov/funding/phase2bridgeaward.asp>





PHASE I – R41, R43

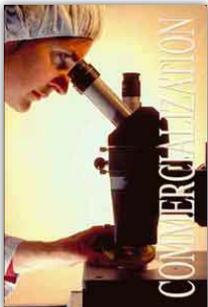
- Feasibility Study
- \$150K and 6-month (SBIR) *
- or 12-month (STTR) Award



PHASE II – R42, R44

- Full Research/R&D
- \$1M and 2-year Award (SBIR & STTR) *
- Commercialization plan required

Phase II Bridge Award



PHASE III

- Commercialization Stage
- Use of non-SBIR/STTR Funds

* Note: Actual funding levels may differ by topic.

Competing Renewal Program for SBIR Phase II Awards

- Provides additional NIH funding to extend selected projects
- Involves another peer-review cycle to evaluate progress & future plans
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners earlier in the development process

A thick, brown, curved arrow pointing from the right side of the list towards the question below.

How does NCI accomplish this goal?

- NCI gives competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., $\geq 1:1$ match)

“...Applicants are expected to leverage their previous NIH SBIR support, as well as the opportunity to compete for additional NCI funding under this [funding announcement], to negotiate and attract third-party financing needed to advance a product or technology toward commercialization...”

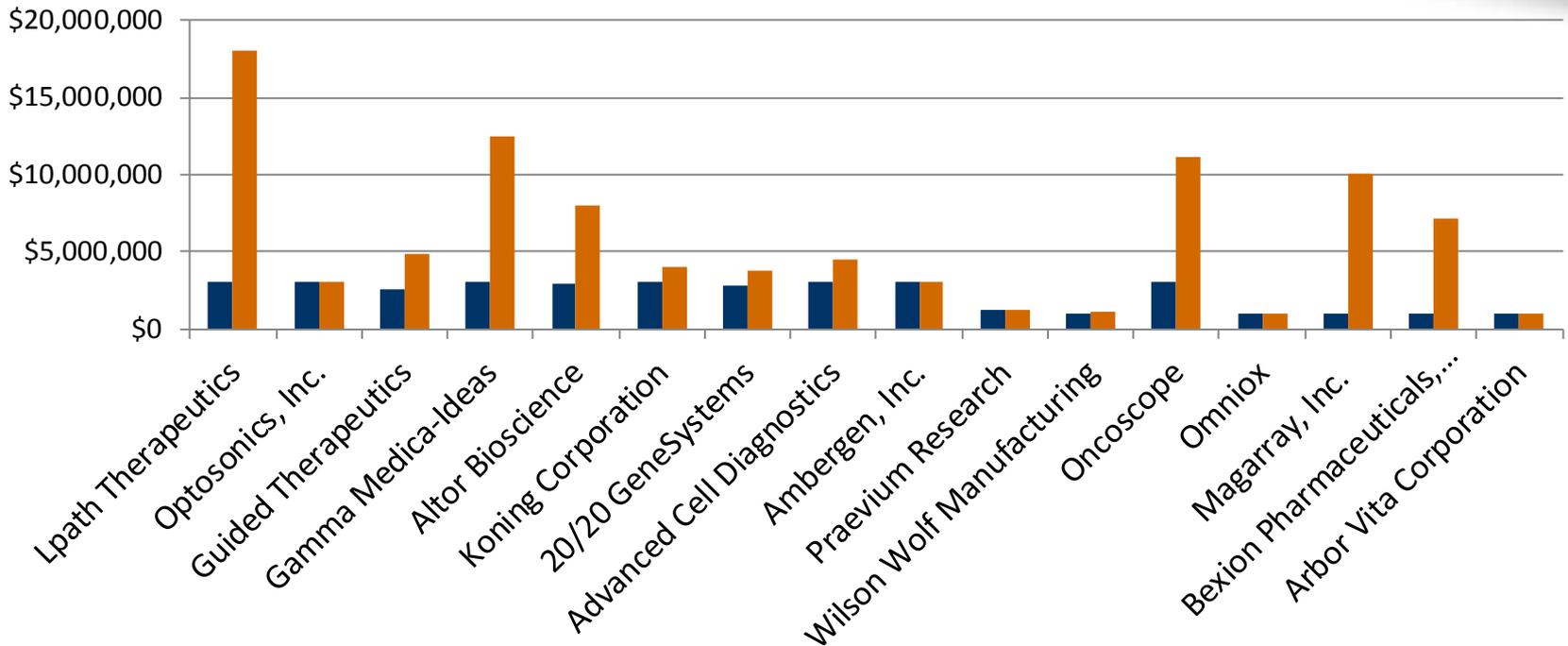
Benefits to the NCI

- Opportunity to leverage millions of dollars in external resources
- Valuable input from third-party investors:
 1. Rigorous commercialization due diligence prior to award
 2. Commercialization guidance during the award
 3. Additional financing beyond the Bridge Award project period

Benefits to third-party investors

- Opportunity to partner with small businesses to develop & commercialize:
 1. Technologies that have been vetted by NIH peer-review, **AND**
 2. Projects for which substantial proof-of-concept data already exists
- **Opportunity to share in the early-stage investment risk with the NCI**

16 Bridge Awards To Date



NCI Total **\$35,262,319**

Third-Party Investments **\$94,300,756**

Leverage **> 2 to 1**



Section III.3 (Eligibility Information)

General Requirements

The Phase IIB Bridge Award application must represent a continuation of the R&D efforts performed under a previous Federally-funded SBIR or STTR Phase II award. Phase IIB Bridge Award applications may be predicated on the following categories of prior Phase II awards:

- SBIR Phase II grant or contract awards funded by any Federal agency
- STTR Phase II grant or contract awards funded by any Federal agency

NOTE: Applicants who intend to submit a Phase IIB Bridge Award application that is predicated on a Phase II award funded by a Federal agency other than the NIH or a previous Phase II contract award **MUST** contact the SBIR Development Center prior to submission, so that the NCI can properly arrange for such applications to be accepted.

The proposed R&D must fall within the technical scope of this FOA as described under Section I (Specific Objectives for SBIR Phase IIB Bridge Award Applications)

Cancer Therapeutics

- Small molecule anticancer agents
- Anticancer biologics, including therapeutic vaccines
- Multifunctional cancer therapeutics based on nanotechnology
- Anticancer drug delivery systems

Cancer Imaging Technologies, Interventional Devices & *In Vivo* Diagnostics

- Medical devices for *in vivo* cancer imaging and image-guided interventions
- Radiation therapy devices and other ablative techniques
- Cancer imaging agents, including imaging radiopharmaceuticals and nanotechnology-based contrast agents
- Devices and technologies for *in vivo* cancer diagnostics
- Devices and technologies that directly enable the delivery of cancer therapies

In Vitro and *Ex Vivo* Cancer Diagnostics and Prognostics

- Molecular diagnostics and prognostics, including *in vitro* diagnostic multivariate index assays (IVDMIA)
- Image analysis tools for diagnosis
- Spectroscopic techniques for *in vivo* and *ex vivo* tissue analysis

- To be responsive to this FOA, the development activities completed under the previous SBIR or STTR Phase II award MUST provide the appropriate technical foundation to justify continued development of the technology for a cancer-relevant indication/use
- Platform technologies that were initially developed for a non-cancer indication/use (e.g., SBIR or STTR Phase II projects funded by an NIH Institute/Center other than the NCI, or SBIR or STTR Phase II projects funded by a Federal agency other than the NIH) may be responsive only if the earlier data demonstrates technical proof-of-concept that is scientifically relevant to the cancer indication/use
- To be responsive under this FOA, the aims of the project must focus on a cancer-relevant indication/use as the primary product or service

Award Budget

Budgets up to \$1,000,000 total costs per year may be requested

Award Project Period

Project periods up to 3 years may be requested

Applicants may not exceed these limits!!

Supplemental Information Requested for all Bridge Applications

Statement of Need (included within the 12-page Commercialization Plan)

Applicants **MUST** provide a concise Statement of Need. This statement is **EXPECTED** to provide answers to the questions listed below:

- What is the perceived “Valley of Death” for the product/technology under development?
- Why is additional government funding critically needed to accelerate the development of the product or technology toward commercialization? Specifically, what activities are being proposed under this FOA that would not otherwise be possible through independent third-party investments OR would be significantly delayed without additional NIH support?
- To what extent would a possible award under this FOA advance the product or technology far enough to attract sufficient, independent third-party financing and/or strategic partnerships to carry out full commercialization?

Fundraising Plan (included within the 12-page Commercialization Plan)

Consistent with achieving the goals of this program, applicants are expected to provide a Fundraising Plan. This plan is expected to include the following information:

- A detailed and specific plan for securing substantial, independent third-party investor funds
 - Any third-party investment support received up to one (1) year prior to the application receipt date may be counted toward the total
- The type(s) of independent third-party investor funds (i.e., cash, convertible debt, etc.) that will be secured during the project period
- The source(s) of independent third-party investor funds (e.g., venture capital, state funds) that will be secured during the project period
- The total amount of independent third-party investor funds that will be secured during the project period
- The anticipated schedule for receiving independent third-party investor funds, including any relevant terms and conditions stipulated by the investors and/or strategic partners

Use of Third-Party Investment Funds (included within the 12-page Commercialization Plan)

- The Federal funds provided by a Phase IIB Bridge Award can only be used for advancing the research-related elements of the project
- **The use of any third-party investor funds will be at the discretion of the small business**

Applicants should provide sufficient information to demonstrate a substantial, value-added contribution toward the commercialization of the product or service, including answers to the following questions:

- What are the specific activities that the third-party investor funds will support?
- Have the investors attached any restrictions/triggers/milestones to future payments (i.e., tranches)? If so, what are they?

SBIR/STTR Commercialization History (included within the 12-page Commercialization Plan)

The following questions should be addressed for all SBIR/STTR awards received from ANY Federal agency:

- Has the company gone through any name changes within the past 5 years? If so, then all previous company names should be listed in the application.
- Is the company a subsidiary or a spin-off? If so, then the name of the parent company should be provided.
- What percentage of the company's revenue was derived from SBIR/STTR funding during each of the past 5 years, including both Phase I and Phase II awards? Applicants should report a percentage value for each year individually.
- What is the total number of SBIR/STTR Phase II awards that the company has received from the Federal government? For each award, companies should provide the award number, the award amount, project duration, and the name of the awarding agency.
- What are the total revenues that have been generated to date as a result of the commercialization of the SBIR/STTR projects funded within the past 5 years?

Letters of Support

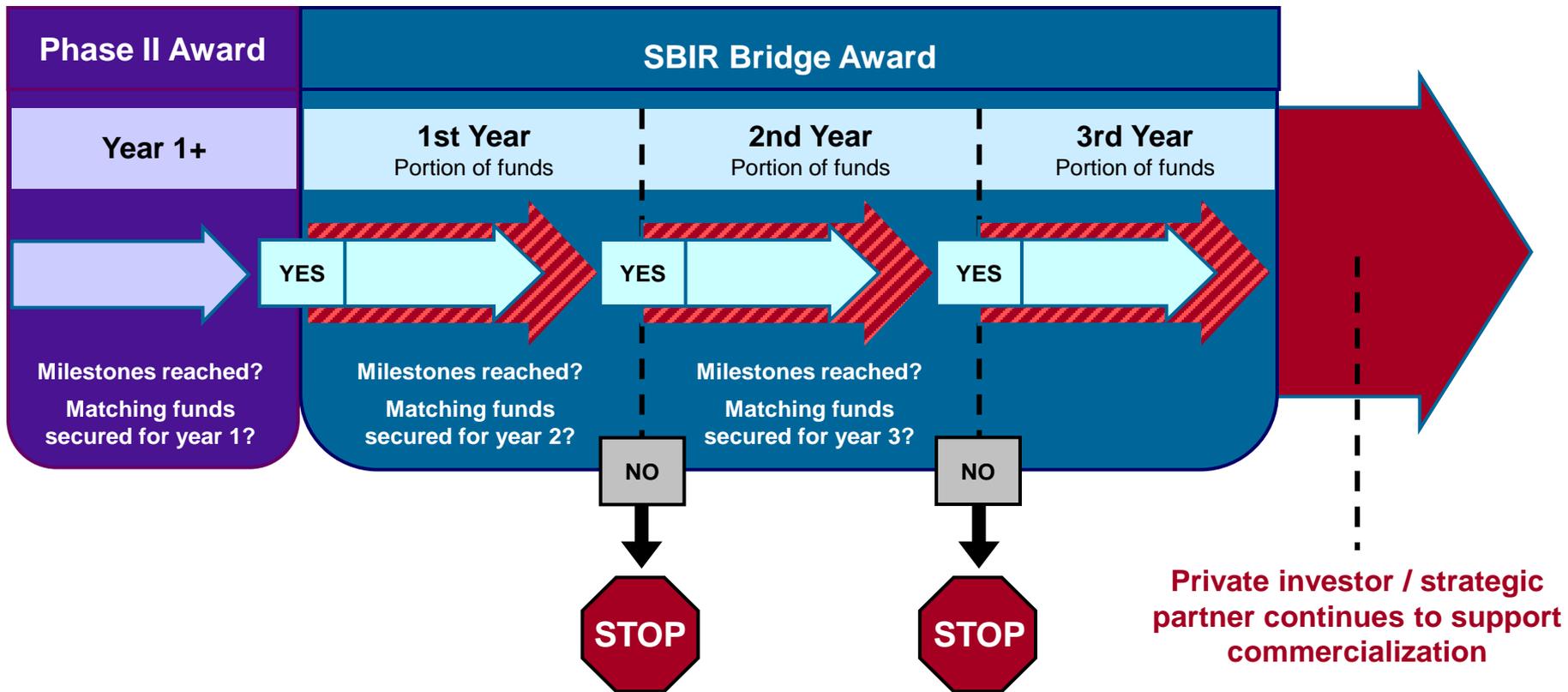
- In addition to standard letters of support documenting collaborations, access to expertise, or to unique research resources, etc, include letters of support documenting commitments from third-party investors
- Letters of support from these institutional partners should indicate any actual or planned/conditional financial commitment as a specific dollar figure or range, consistent with the instructions provided under Section IV.2, Other Attachments, “Fundraising Plan”
- Appropriate documentation of third-party investor commitment(s) may include a conditional letter of support stating that the third-party funding is contingent upon NIH selecting the application for an award
- Documentation of support from third-party investors should corroborate the Fundraising Plan

Supplemental Information: [other] documents related to third-party investors and their commitment

- Include documentation of support from third-party investors, such as term sheets or redacted bank statements or other appropriate documents (other than letters of support)
- Collate all such documents in one file (with a list of the attached documents at the beginning)
- Use the filename "Third-Party Investors"; (Note that this filename will become a bookmark in the application)

Milestone-Based Awards

Ability to raise matching funds is a component of the Phase II Bridge Award



- Significance *
- Investigators
- Innovation
- Approach *
- Environment

PLUS some additional review considerations

Submit Your Questions

- Submit your questions any time via the Q&A box on the right-hand side of your screen.
- If you do not see the Q&A box, you can expand it by hovering over the **green bar** at the top of your screen and clicking the Q&A button.



- Please submit questions of a general nature via the Q&A Box with no proprietary information.
- Please be advised we will not answer questions specific to your project in this webinar.
- You can also send your questions to NCIsbir@mail.nih.gov
- The webinar slides, audio recording, and Q&A will be published to the website, <http://sbir.cancer.gov>
- All webinar registrants will be emailed links to access webinar slides, audio recording, and Q&A

PLEASE SHARE YOUR FEEDBACK WITH US

NCI SBIR Development Center

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Phone: 240.276.5300

<http://sbir.cancer.gov>

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Thank You!

