



The NCI SBIR Program



NCI SBIR Funding Opportunities



NCI Has Moved to More Targeted Funding Opportunities



Goals:

- **Improve success in commercialization by focusing on more directed research**
- **Invest in the technology priorities of NCI that also have greatest potential for commercialization**
- **Catalyze targeted technology development and draw private sector investment in specific areas**

- **One of the largest sources of early stage life sciences funding in the country.**
 - **A stable and predictable source of funding**
- **Intellectual property rights are retained by the small business concern**
- **Not a loan – no repayment is required**
- **Doesn't impact stock or shares in any way (no dilution of capital)**
- **Provides recognition, verification and visibility**
- **Can be a leveraging tool to attract other funding (VC, etc.)**

- Applicant must be a Small Business Concern (SBC)
- Organized for-profit U.S. business
- 500 or fewer employees, including affiliates
- PD/PI's primary employment (i.e., >50%) must be with SBC at the time of award and for duration of the project period
- At least 51% U.S.- owned by individuals and independently operated

OR

At least 51% owned and controlled by another (one) business concern that is at least 51% owned and controlled by one or more individuals

- **The National Cancer Institute high-priority research areas include, but are not limited to:**
 - Cancer Biology
 - Cancer Prevention
 - Cancer Therapeutics
 - E-Health and Software Development
 - Imaging Technologies
 - Interventional Devices
 - *In Vitro* and Companion Diagnostics
 - Nanotechnology
 - Proteomics
 - Radiation Therapy

SBIR/STTR Omnibus Grant Solicitation

Release: January

Receipt Dates: April 5, August 5, and December 5

SBIR Contract Solicitation (NIH, CDC)

Release: August

Receipt Date: Early November

SBIR Bridge Award

Release: Varies

Receipt: Varies

NIH Guide for Grants and Contracts

Release: Weekly

Receipt Dates: Varies

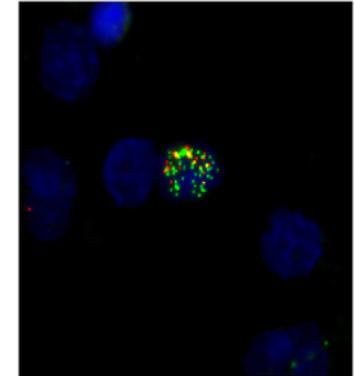
For more information visit:

<http://sbir.cancer.gov>

Point of Care Analysis for Circulating Tumor Cells (CTCs)

➤ **Project Goals**

- ❑ To develop Point of Care devices and methods of CTC detection, enumeration, isolation, removal and molecular analysis
- ❑ To provide tools with cost and/or performance advantages over current technologies



*A CTC detected using
ACD's RNAscope™*

Companion Diagnostics

➤ **Project Goals**

- ❑ To provide noninvasive tests to evaluate molecular profiles of patients
- ❑ To develop companion diagnostics to select patients for whom a particular therapeutic regimen will be safe and effective

***Topics also included emerging technology
areas in cancer therapeutics, imaging, and diagnostics***

Highlights:

- Launched in January 2011
- Designed to assist companies working on therapeutics, devices, diagnostics, and other technologies requiring regulatory approval
- Open to NCI SBIR & STTR Phase II grantees and contractors with projects that are current, or have ended within the last two years
- Provides up to 30 hours of regulatory consulting time to assist companies in developing a regulatory approval strategy and plan



***Helping Companies Bridge
the “Valley of Death”***



Eligibility Requirements

- Application must represent a continuation of the R&D efforts performed under a previously funded NIH SBIR Phase II grant or contract award or one that ended in the past two years.
- Meet SBIR Program eligibility requirements

Incentive Structure

- **Helps early-stage companies cross the “Valley of Death” by:**
 - Facilitating partnerships with third-party investors & strategic partners
 - Incentivizing third-party investments earlier in the development process
 - **NCI is sharing in the investment risk with other investors**
- **Gives competitive preference and funding priority to applicants that can raise third-party funds (i.e., minimum 1:1 match)**
 - Affords NIH the opportunity to leverage millions in external resources
 - Provides valuable input from third-party investors in several ways:
 1. Rigorous commercialization due diligence prior to award
 2. Commercialization guidance during the award
 3. Additional financing beyond the Bridge Award project period

Technical Scope: Cancer Therapies, Diagnostics & Imaging Technologies

- Need for large amounts of capital for clinical validation and FDA approvals
- Opportunity to make a significant impact on many projects in the SBIR portfolio

Mechanism & Budgets

- Uses the SBIR Phase II (R44) competing renewal mechanism
- **Provides up to \$1 M per year for up to 3 years**
- Available to current Phase II grant and contract awards, and those that ended within last 2 years

Preferred Third-Party Matching Funds

- Cash, liquid assets, convertible debt

Sources of Funds

- Another company, venture capital firm, individual “angel” investor, foundation, university, state or local government, or any combination

- **Affords investors/strategic partners the opportunity to leverage up to \$3 million in NCI funding**
- **NCI takes no equity position in the companies**
- **All companies applying for the program have been vetted through the NIH peer review twice (Phase I and Phase II)**
- **NCI will be a partner with you in helping move these companies into the clinic and towards commercialization**

Example: How the Bridge Award Would Apply in the Area of Drug Development

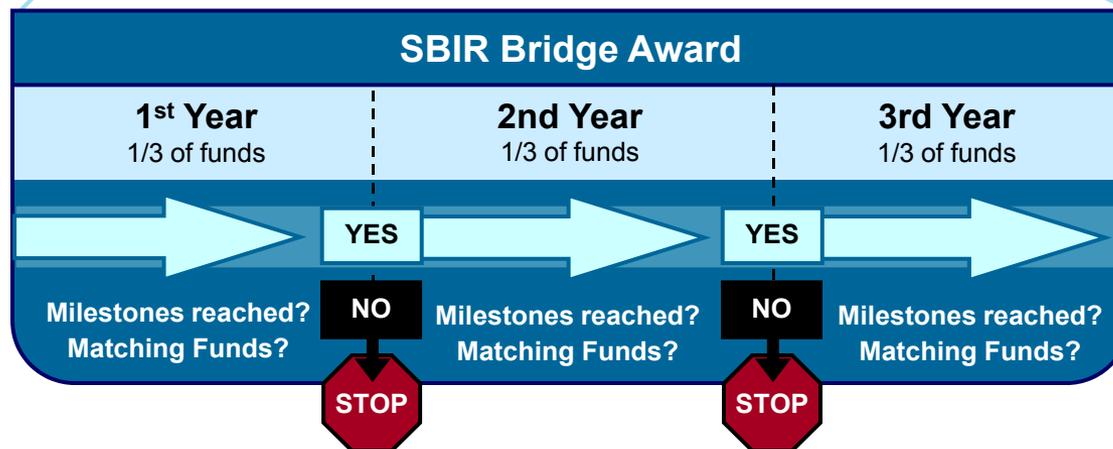


“Valley of Death”

SBIR Bridge Award addresses the problem by bridging the **“Valley of Death”**

SBIR Bridge Award allows NIH to share investment risk by incentivizing investors or strategic partners to evaluate projects and commit funds much earlier

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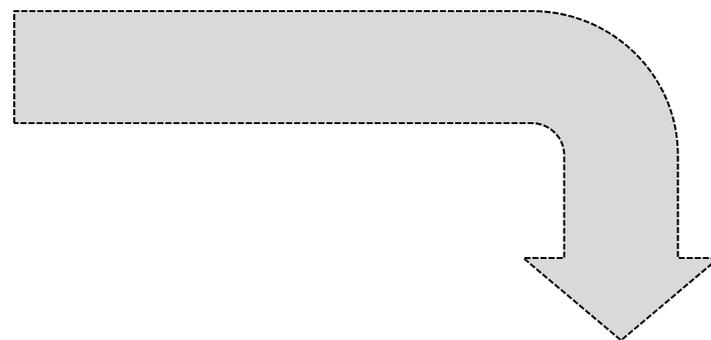


Third-party Investment

Cumulative for 10 Bridge Awards Made in FY2009 & FY2010



Traditional Venture Capital	\$21,500,000
Strategic Partners	\$24,200,000
Other Investment Firms	\$5,500,000
Individuals/Other	\$11,750,000



Investor Total (3 yrs)	\$62,950,000
NCI Total (3 yrs)	\$27,395,816

Leverage >2.3 to 1

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For more information on companies who have successfully leveraged SBIR funding, please visit:
<http://www.sbir.cancer.gov/success/>

Sign-up for funding and program updates
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