The NCI SBIR Program
Presentation at AACR
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Today's Presentation
Program Overview
NCI Funding Opportunities
New SBIR Bridge Award
Tips on Submitting Applications

Overview

History
Established through the Small Business Innovation Development Act of 1982 with aims to:

- Stimulate technological innovation
- Use small business to meet federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from federal R&D

Program Descriptions
SBIR: Set-aside Program for Small Business Concerns to engage in Federal R&D with potential for commercialization – set aside 2.5%

STTR: Set-aside Program to facilitate Cooperative R&D between Small Business Concerns and U.S. Research Institutions with potential for commercialization – set aside 0.3%

A $105M Program at the NCI

PHASE I – R41, R43

- **Feasibility Study**
- **$100K and 6-month (SBIR) ***
- ***or* 12-month (STTR) Award**

PHASE II – R42, R44

- **Full Research/R&D**
- **$750K and 2-year Award (SBIR & STTR) ***
- **Commercialization plan required**

PHASE III

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

*** These funding levels are guidelines. You should request the budget appropriate to accomplish the goals of the project.**

Why are SBIR and STTR Important?
NCI's primary resource for enabling commercialization of innovative high impact technologies, such as:

- Cancer Diagnostics
- Cancer Imaging
- Small Molecules and Biologics
- Electronic Health & Education Tools

Provides incentive to academic investigators to translate technology (new company formation)

SBIR Program is one of the rare sources of seed funding for companies which is stable and predictable

NCI SBIR Funding Opportunities

NIH Issues Multiple SBIR Solicitations

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**

NIH Guide for Grants and Contracts
Release: **Weekly**
Receipt Dates: **Various**

For more information visit:
http://sbir.cancer.gov/

NCI is Moving to More Focused Solicitations

- Goal is to improve success in commercialization by focusing on more directed research.
- Invest in the technology priorities of NCI that also have potential for commercialization
- Catalyze targeted technology development and draw private sector investment in areas such as drug development and cancer imaging
- Significantly increase the use of SBIR contracts.

NCI SBIR Technology Priorities – Last Cycle

- Development of Molecular Pharmacodynamic Assays for Targeted Therapies
- System to Analyze and Support Biomarker R&D Strategies
- Development of Anticancer Agents
- Innovative Methods for Manufacturing Safe, Effective Cancer Therapeutics
- Innovative Strategies to Protect Radiosensitive Organs and structures During Radiation Therapy
- Quantitative Tissue Imaging For Clinical Diagnosis and Treatment
- Antibody Array for Cancer Detection and Diagnosis
- Novel and Improved Assays for Detecting Epigenetic Modifications
- Nanotechnology Imaging and Sensing Platforms for Improved Diagnosis of Cancer
- Mobile Computing for Consumer-centered Cancer Prevention and Control

New SBIR Bridge Award

Phase II SBIR and Commercialization Success

Today, many awardees complete the SBIR Phase II award without advancing the technology far enough to attract private investment

- Significant resources are required for getting through the FDA approval process
- This funding gap is known as the "Valley of Death"

SBIR Phase II Bridge Award
Follow-on to SBIR Phase II

- Goal to help 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 by
        - Sharing in the investment risk with third-party investors

RFA Incentive Structure

- Gives competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e., minimum 1:1 match)
    1. Affords NIH the opportunity to leverage millions in external resources
    2. Third-party investors can provide valuable input in several ways:
    3. Rigorous commercialization due diligence prior to award
    4. Commercialization guidance during the award
    5. Additional financing beyond the Bridge Award project period

Original RFA Concept
Technical Scope: Cancer Therapies & 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 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

Launched May 14, 2008

- **Two Receipt Dates:**
  - September 19, 2008
  - February 27, 2009

- **Special Review Criteria**
  - Balanced consideration of technical and commercial merits
  - Detailed requirements for IP, regulatory and financing plans
  - Complete disclosure of applicant's SBIR commercialization history

  - ➢ **Applications with strong financing plans are rewarded with higher score**

Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH), (http://www.nih.gov)

Components of Participating Organizations
National Cancer Institute (NCI), (http://www.cancer.gov)

Title: SBIR Phase II Bridge Awards to Accelerate the Development of New Cancer Therapies and Cancer Imaging Technologies Toward Commercialization (SBIR [R44])

Announcement Type
New

Request For Applications (RFA) Number: RFA-CA-08-021

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (http://www.grants.gov) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission date. See Section IV.

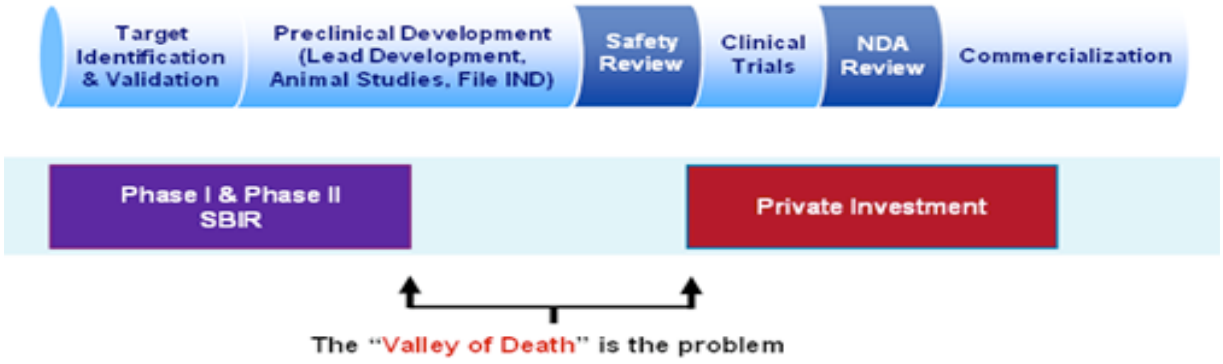
Apply for Grant Electronically

For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at http://grants.gov/CustomerSupport

Catalog of Federal Domestic Assistance Number(s)
93.394, 93.395

Key Dates
Release/Posted Date: May 14, 2008

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



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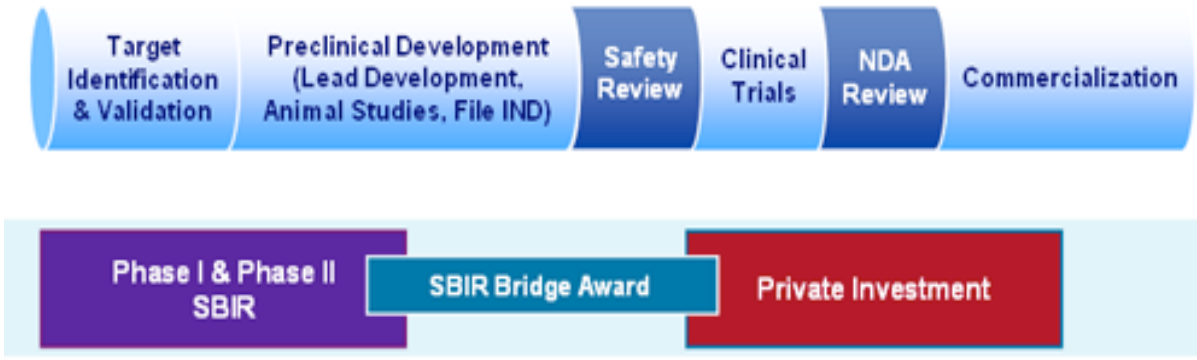

SBIR Bridge Award addresses the problem by bridging the "Valley of Death"
SBIR Bridge Award allows NIH to share investment risk by incentivizing investors or strategic partners to evaluate projects and commit funds much earlier

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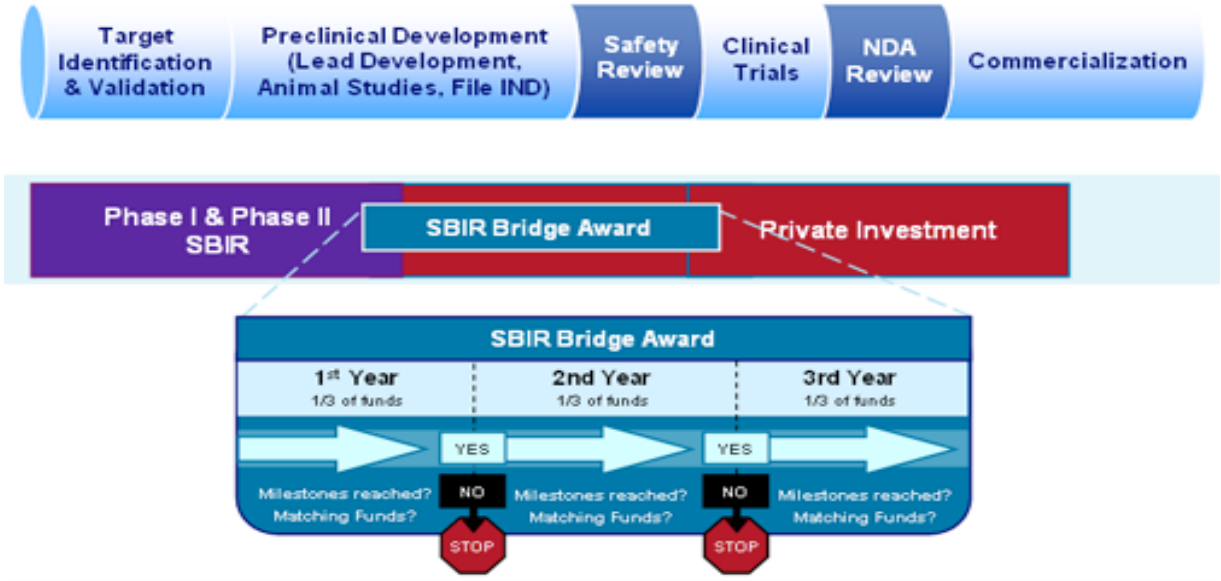

Expanded Technical Scope
(FY10 reissuance)
Therapeutics

- Anticancer drugs and drug delivery systems
- Small molecules, biologics and vaccines

Devices for Cancer Therapy
- Devices for therapeutic (anticancer) use of ionizing radiation
- Other ablative techniques

Imaging Technologies
- Medical devices for in vivo cancer imaging
- Image-guided interventions (e.g., biopsy, surgery, drug delivery)
- Imaging agents

Cancer Diagnostics
- In vitro diagnostics
- Any other diagnostic modality

More Information on NCI SBIR & STTR Website
http://sbir.cancer.gov/

Submitting an Application

Keys to a Strong Application
- Significant, innovative, and focused science
- Significant product and/or commercial potential
    - A product-focused application is more likely to have support of business reviewers
    - A project with sound financial projections is more likely to attract a partner
- Translational research/clinical applications projects should involve the appropriate collaborators
    - Oncologists
    - Pathologists
    - Statisticians

Know NIH Review Criteria

Significance
- **Does the study address an important problem and have commercial potential?**

Approach
- **Are design and methods well-developed and appropriate? Are problem areas addressed?**

Innovation

- **Are there novel concepts or approaches? Are the aims original and innovative?**

Investigator

- **Is the investigator appropriately trained and capable of managing the project?**

Environment

- **Does the scientific environment contribute to the probability of success? Is the environment unique?**

Commercialization

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

Key #1
Start Application Process Early!

- Start developing your application as early as possible. You need time to develop a strong proposal.
- Seek help of experienced applicants early in process
- Assemble a strong scientific team
    - If you have a weakness or gap in expertise, fill it early

Key #2
Consider Your Company's Strengths and Weaknesses

- Consider your company's strengths
    - Try to exploit those strengths to address a specific NIH Program initiative
- Consider your weaknesses too
    - It is rare that a small company will have all the necessary expertise for a strong application
    - If you have no track record of commercialization, consider getting a partner who does
- Partner with other companies or academics to fill gaps
- Contact NIH Program Director in advance to discuss your proposal and receive feedback
- Review similar currently funded projects in the NIH CRISP database http://crisp.cit.nih.gov/

Key #3
Always Consider the Reviewers

- Who is going to review your application?
  - 10 or more on the Review Panel who will score your application
  - However, primary review by 2-4 persons with appropriate expertise assembled by SRA
  - Combination of academic and business professionals

Key #3
Always Consider the Reviewers

- What are they looking for?
  - Readable and understandable application
    - Do not assume they will know everything you know
    - You understand your application best so convey it to them
    - Clear and concise language, "lay summary"
  - Clear plan for Phase I, II and commercialization
  - Feasible methods
  - Appropriate objective tests of success for each Specific Aim
  - Promising preliminary data are very influential
  - Solid letters of support for commercialization

Key #3
Always Consider the Reviewers

- Read your material critically as if you were the Reviewer
  - What are the weaknesses?
  - Point out potential difficulties, do not hide them
  - Suggest ways to address them or provide rationale
  - Recruit an independent reader

Provide alternative methods if a particular approach is not successful
Help the Reviewer write his analysis

Key #3
Always Consider the Reviewers

Be realistic about your goals
Provide a feasible timetable for key objectives

Be realistic about your budget

Ask Program Director for early guidance

Application Checklist

- Have you honestly assessed the commercial viability of your technology?
- Do you have a talented professional to be a PI?
- Is the PI supported by the right team? Does he or she have the time?
- Do you have the resources to write the grant application or contract proposal?
- Do you have the resources and capabilities to execute?
- Do you have the business resources needed for a successful launch?

If you aren't funded the first time…

- Use peer review to improve your technology and presentation
    - Reviewers often spot errors in the proposal
    - Reviewers will let you know if what you are proposing has been done before
- If peer reviewers "didn't get your proposal"
    - Customers, investors, and employees may not get it either
    - Fix errors, improve your presentation
- It's always painful not to be funded, but at least you get the feedback
- Explore opportunities to serve on NIH peer review panels
    - Exposure to grantsmanship & insight into the review process
    - Meet bright colleagues

http://sbir.cancer.gov/

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Register on web site for funding opportunity updates