Secrets of NIH Small Business Grant Applications

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May 7, 2012

Particularly Important Information Is Highlighted in Red

IMMUNOLOGY 2012
99th Annual Meeting

NIH Small Business Research Funding Opportunities
http://grants.nih.gov/grants/funding/sbir.htm

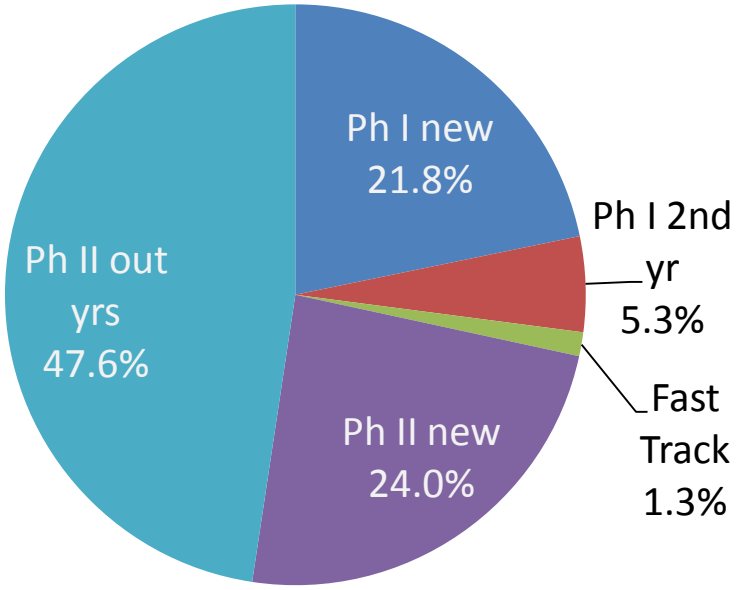
- Funding Opportunities
  - Small Business Innovation Research (SBIR)
  - Small Business Technology Transfer Research (STTR)
- Eligibility
- Receipt dates
- Program descriptions and research Topics
- Electronic submission information
- Application review process
- Policy information
- Grant preparation resources
- NIH Small Business Conference information

SBIR and STTR Are Sequential Multiphase Programs

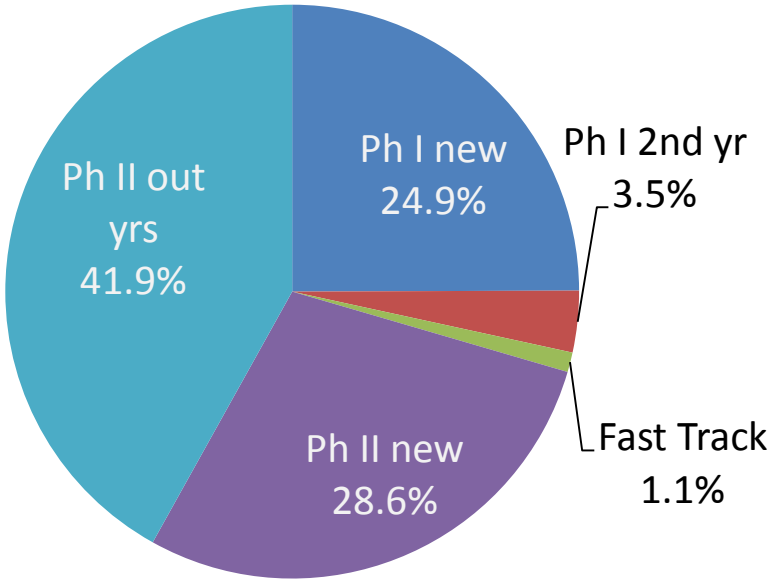
- Phase I Awards (1 or 2 years)
  - SBIR Phase I Median Award $208K/year (FY2011)
  - STTR Phase I Median Award $227K/year (FY2011)
  - Awards to about 10.7% of applications (FY2011)
- Fast-Track – Combined Phase I/II application
- Competing Phase II (renewal)
  - For FDA related products
  - Awards up to $1M per year for 2 to 3 years
- Phase III
  - Remaining steps of commercialization
  - Not funded by government. Funded by other sources

NIH FY2011 SBIR and STTR Funding

FY 2011 SBIR FUNDING
$ 572.7 Million



FY 2011 STTR FUNDING
$ 73.5 Million



SBIR (R43 and R44)
Small Business Innovation Research

- **Business applies for and receives award**
- 2.5% of NIH extramural research budget
- About $578M in competing and noncompeting FY2011 NIH awards
- Principal Investigator (PI) in single PI application must be employed over 50% by company.
- Multiple PI applications allowed – One as "Contact PI"
  - Leadership plan required
  - Contact PI employed over 50% time by company.
  - Academic PI allowed but not as a Contact PI
- Subcontracting allowed but not required
  - Up to 33% in Phase I
  - Up to 50% in Phase II

STTR (R41 and R42)
Small Business **T**echnology **T**ransfer **R**esearch

- **Business applies for and receives award**
- 0.3% of NIH extramural research budget
- About $74M in competing and noncompeting FY2011 NIH awards
- Requires research institution partner that conducts a minimum of 30% of the work (funds)
- Business must conduct minimum of 40% of work
- Remaining funds, if any, can be used for consultants or other subcontractors
- Contact PI
  - Must commit 10% effort
  - Need not be employed by business
  - Full-time academic employee allowed
  - Need not receive salary from award

Advantages of SBIR and STTR Awards

- SBIR over STTR
  - No research institution partner necessary
  - Flexibility to increase or decrease subcontracting
  - Academic scientist consultant fees on top of salary
- STTR over SBIR
  - Company lacks credible PI
  - Contact PI role essential to academic scientist
  - Potentially better access to academic facilities, intellectual property and support
  - Higher percent Phase I subcontract possible.

SBIR and STTR Company Eligibility Rules

- Majority owned and controlled by U.S. individuals and not by corporations.
- Principal place of business in U.S.
- SBIR and STTR funded research must be conducted entirely in the U.S.
- Company owns or leases distinct and separate facilities where SBIR and STTR research will be conducted.
- Small = 500 or fewer employees in the small business and all its affiliates.
- Opportunities for foreign and VC-owned companies.
  - Collaboration
  - Maybe ownership under reauthorization.

SBIR & STTR Phase I Application Components
Requires Lots of Reading – Minimal Writing

Pages	Section
1	Introduction – Resubmitted or New Applications Only
1	Specific Aims (milestones)
6	Research Strategy
	a. Significance
	b. Innovation
	c. Approach
	• Preliminary Studies for New Applications
	• Progress Report for Renewal/Revision Applications
	• Research Design: Strategy, Methodology, Analyses
N/A	Environment – How do resources contribute to project?
4	Investigator – Biographical Sketch
	a. Personal Statement –Qualifications for Project
	b. Publications – Maximum of 15 Relevant to Project

Online NIH "Due Diligence" Tools Are Your Key to Success

A. Small Business Research Funding Opportunities
B. NIH Center for Scientific Review (CSR)
C. NIH Research Portfolio Online Reporting Tools
    1. Strategic Plans and Visions
    2. Success Rates
    3. NIH RePORTer
D. PubMed

Special Emphasis Panels Score SBIR/STTR Applications

- The percent of reviewers affiliated with companies varies from about 20% to 60%.
- Reviewers read, discuss, and give an Impact score to applications they think belong among the best 50%. Other applications not discussed or scored (triage).
- Only a few reviewers are your application's Subject Matter Experts and they greatly influence your score.
- Reviewers average Impact score is multiplied by 10 to give a final score of between 10 and 90 (10=best).

Characteristics of an Outstanding Small Business Grant Application *For Reviewers*

- Addresses a significant problem *for reviewers*
- Leads to an innovative product *for reviewers*
  - Has an impact on the problem
  - Offers high financial reward for business
  - Exit strategy can be achieved in reasonable time
- Reviewers judge probability of success judged by
  - Investigators prior accomplishments
  - Approach and experimental design
  - Preliminary data
  - Company and collaborator resources

FY2011 NIH Phase I Applications

Type	Received	Funded	Award Rate
SBIR All	5597	578	10.3%
Initial	4387	378	8.6%
Revisions	1210	200	16.5%
Median Award/Yr		$208K	
STTR All	616	84	13.6%
Initial	475	52	10.9%
Revisions	141	32	22.7%
Median Award/Yr		$227K	

FY2011 NIH Phase II Applications

Type	Received	Funded	Award Rate
SBIR All	749	204	27.2%
Initial	463	128	27.7%
Revisions	286	76	26.6%
Median Award/Yr		$597K	
STTR All	111	37	33.3%
Initial	65	25	38.5%
Revisions	46	12	26.1%
Median Award/Yr		$479K	

SBIR and STTR Omnibus Solicitations
Receipt, Review, and Award Dates

Awards Within Payline

	~ 33%	~ 33%	~ 33%
Receipt (AIDS)	Apr 5 (May 7)	Aug 5 (Sep 7)	Dec 5 (Jan 7)
Review	Jun-Jul	Oct-Nov	Feb-Mar
Council	Sep-Oct	Jan-Feb	May-Jun
Estimated Award	Nov	Mar	Jul
50% Awarded	~Apr (12 mo)	~Jun (10 mo)	~Aug (8 mo)

SBIR/STTR Long-Term Funding Timeline
Example: December Receipt Date

Phase I

Dec 2007 Submit Phase I application
Jun 2008 Application reviewed
Sep 2008 Grant Funded for 2yr
Aug 2009 Complete Phase I Sp. Aims

Phase II

Dec 2009 Submit Phase II application
Jun 2010 Application reviewed
Sep 2010 Grant funded for 3yr

Dec 2012 Submit Phase II renewal
Jun 2013 Application review
Sep 2013 Grant funded for 3yr

Sep 2014 Seek venture funding, licensing or acquisition

Ways Faculty and Students Can Tap into SBIR and STTR Grants

- Consultant on small business grant
- Subcontractor on small business grant
- Principal investigator on small business grant
  - Contact PI on STTR grant
  - Non-Contact PI on Multiple PI SBIR grant
- Start a small business with grant funds
- Shift careers with NIH SHIFT Award

Ways Academic Institutions Can Tap into SBIR and STTR Grants

- Enable real-world experience for students and faculty
  - Identify problems
  - Propose solutions
  - Prepare funding applications
  - Great learning and writing exercise
- Fund faculty consulting and student research
- Create intellectual property that can be licensed for downstream royalties
- Foster relationships with businesses
- Create potential employment for students and faculty
- Create new businesses
- Obtain equity in new businesses
- Business incubator facilities

Deciphering Funding Opportunity Announcements SEPs Always Review SBIR and STTR Applications

- **PA** – Program Announcement reviewed by NIH Center for Scientific Review (CSR), with some advance review committee information.
- **PAR** – Program Announcement Reviewed by an IC usually with single-meeting review committee.
- **PAS** – Program Announcement Reviewed by an IC with set-aside (dedicated) funds and single-meeting review committee.
- **RFA** – Request for Applications Reviewed by an IC with set-aside funds usually one-time solicitation and single-meeting review committee.

SBIR Omnibus Solicitation (Parent Announcement)

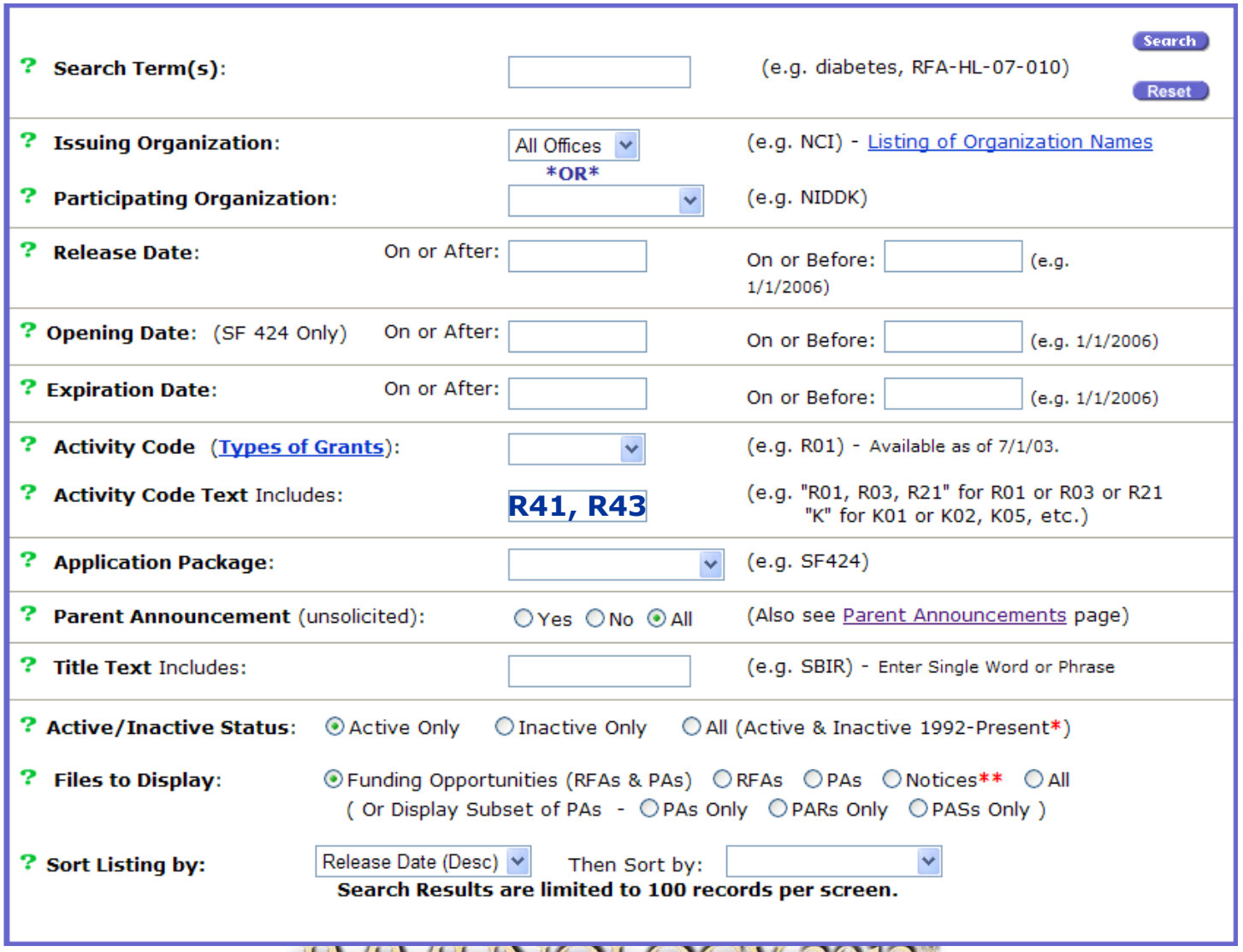
http://grants.nih.gov/grants/guide/pa-files/PA-11-096.html

Funding Opportunity Title	**PHS 2011-02 Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])**
Activity Code	R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I, Phase II, and Fast-Track
Announcement Type	Reissue of PA-10-050
Related Notices	• February 8, 2011 - See Notice NOT-AI-11-030 The purpose of this Notice is to highlight NIAID's interest in receiving grant applications to develop strategies, methods and/or tools to optimize influenza vaccine production.
Funding Opportunity Announcement (FOA) Number	**PA-11-096**
Companion FOA	PA-11-097, STTR R41/R42- Phase I, Phase II, and Fast Track
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal DomesticAssistance (CFDA) Number(s)	93.061, 93.103, 93.113, 93.121, , 93.136, 93.172, 93.173, 93.213, 93.242, 93.262, 93.273, 93.279, 93.283, 93.286, 93.307, 93.361, 93.389, 93.393, 93.394, 93.395, 93.396, 93.399, 93.647, 93.837, 93.838, 93.839, 93.846, 93.847, 93.853, 93.855, 93.856, 93.859, 93.865, 93.866, 93.867, 93.879
FOA Purpose	This Funding Opportunity Announcement (FOA) issued by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Administration for Children and Families (ACF) invites eligible United States small business concerns (SBCs) to submit Small Business Innovation Research (SBIR) grant applications. United States SBCs that have the research capabilities and technological expertise to contribute to the R&D mission(s) of the NIH, CDC, FDA or ACF awarding components identified in this FOA are encouraged to submit SBIR grant applications in response to identified topics (see PHS 2011-2 SBIR/STTR Program Descriptions and Research Topics for NIH, CDC, FDA and ACF.)

Key Dates

Posted Date	January 24, 2011
Open Date (Earliest Submission Date)	March 5, 2011
Letter of Intent Due Date	Not applicable
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization.
AIDS Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization.

NIH Advanced Funding Opportunities & Notices Search http://grants.nih.gov/grants/guide/search_guide.htm



Search

Reset

? **Search Term(s):** (e.g. diabetes, RFA-HL-07-010)

? **Issuing Organization:** All Offices (e.g. NCI) - Listing of Organization Names

OR

? **Participating Organization:** (e.g. NIDDK)

? **Release Date:** On or After: On or Before: (e.g. 1/1/2006)

? **Opening Date:** (SF 424 Only) On or After: On or Before: (e.g. 1/1/2006)

? **Expiration Date:** On or After: On or Before: (e.g. 1/1/2006)

? **Activity Code** (Types of Grants): (e.g. R01) - Available as of 7/1/03.

? **Activity Code Text** Includes: **R41, R43** (e.g. "R01, R03, R21" for R01 or R03 or R21 "K" for K01 or K02, K05, etc.)

? **Application Package:** (e.g. SF424)

? **Parent Announcement** (unsolicited): Yes No All (Also see Parent Announcements page)

? **Title Text** Includes: (e.g. SBIR) - Enter Single Word or Phrase

? **Active/Inactive Status:** Active Only Inactive Only All (Active & Inactive 1992-Present*)

? **Files to Display:** Funding Opportunities (RFAs & PAs) RFAs PAs Notices** All

(Or Display Subset of PAs - PAs Only PARs Only PASs Only)

? **Sort Listing by:** Release Date (Desc) Then Sort by:

Search Results are limited to 100 records per screen.

NIH Application Review Criteria and My Interpretations

- Five Core Review Criteria
  - Significance – *Is the problem important?*
  - Innovation – *Will the product make a difference?*
  - Investigators – *Are you qualified for the work?*
  - Approach – *Are your studies well designed ?*
  - Environment – *Do you have the essential resources and collaborators ?*
- Impact Score: The overall impact of proposed research is not an average of five Core Review Criteria.

Significance (Health Problem In People)

- Single narrow disease is best because the application will be assigned to a reviewer who knows and cares about that disease.
- What are the number and composition of the population affected?
- What discoveries are needed? (gaps, roadblocks, etc.)

Focus On A Product, Not On Your Technology

- Core technology builds a business.
- A single use of core technology makes an SBIR/STTR application.
- Advantages of focus on single use:
  - Meets needs of specific problem
  - Targets committed reviewers
  - Demonstrates business acuity
  - Allows additional applications using same core technology
  - Directs different uses of your technology to different ICs and different review groups
- Describe the public health and financial significance of your product.

Innovation (Product)

- Why is your product innovative (better, faster, at lower cost, etc.)?
- What are the public health implications?
- What are the product's financial projections?
- After Phase II, what additional steps will be necessary before your company can realize a profit?

Investigator and Environment: PI Needs Credible Credentials

- Training (where?) and Trainer (who?)
  - Advanced Degree
  - Postdoctoral Experience
- Significant Demonstrated Experience
  - Knowledge of Field and/or Technology
    - Publications (First & Last Author)
    - Presentations at Scientific Meetings
    - Patents
  - Preliminary Data (Some must be applicants)
- Research Team and Collaborators
- Research Resources
- Company Submitting Application

Title – One Product and One Problem in 81 Characters (Innovation and Significance)

- Title should convey two pieces of information.
  - What is your product? (Innovation)
  - What is the public health problem? (Significance)
- Decide on your title before you write your application!
- The remaining sections of your application are just details.

Titles of Real Phase I SBIR Applications

Do these include both a product and a problem?

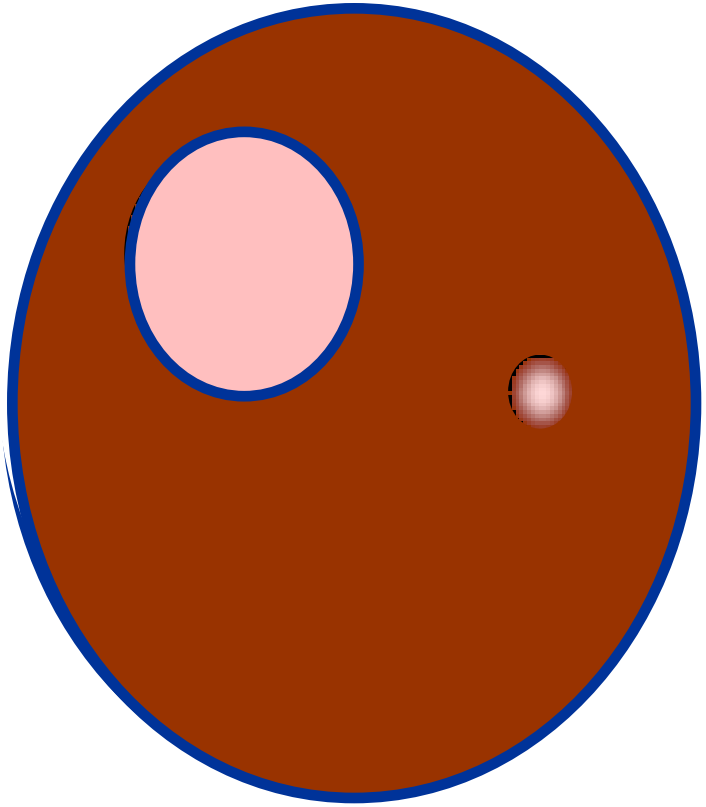
1. Development of Antimicrobial Peptides
2. Antigen Detection Assay for the Diagnosis of Visceral Leishmaniasis
3. Enteric-coated Vector Microparticles for Oral Vaccination
4. Coupled Enzyme Reporter Assay for Proteases
5. An Immunoadhesin Therapy for Gastrointestinal Anthrax
6. Proteolytic Antibodies for Treatment of Psoriasis
7. A Dynamic Web-based Geospatial Data Visualization and Distribution System
8. Virus-like Particle (VLP) Vaccine for RSV
9. Molecular Screen for Antiviral Agents
10. Multi-antigen Peptide Assay for the Serodiagnosis of Lyme Disease

Specific Aims (All Criteria)

- Paragraph 1
  - Problem and its significance
  - Current solutions, gaps, roadblocks
- Paragraph 2
  - Your product
  - Why it is an innovative solution to the problem
- Specific Aims (two or three with bullets for each)
  - No more than necessary to justify Phase II
  - Timeline
  - Environment contribution if applicable
  - Easily assessed by a review committee
  - End point specific aims as opposed to a best effort
    - A best effort specific aim is "to evaluate a number of potential drug candidates."
    - An end point specific aim is "to select the best drug candidate for Phase II study."

Propose Just Enough Work in Phase I to Get to Phase II
Larger Balloons Are More Likely to Be Popped

Review Committee



Your Application

SHIFT Award: Small Businesses Helping Investigators to Fuel the Translation of Scientific Discoveries (R43/R44)

- http://grants.nih.gov/grants/guide/pa-files/PA-10-122.html
- PI SHIFT requirement
  - At time of application, contact PI must be primarily employed by research institution.
  - At time of award, contact PI must be primarily employed by small business.
  - No new investigator advantage or disadvantage.
- Budget – Higher than "Normal"
  - Phase I up to $200K/year for 1 or 2 years
  - Phase II up to $750K/year for 2 or 3 years
- Topics – Any within the mission of the twelve participating Institutes and Centers

SHIFT Connector: Bringing Academic Investigators and Companies Together

- http://funding.niaid.nih.gov/researchfunding/sb/pages/shift.aspx
- NIAID hosts pilot SHIFT Connector site to help investigators and businesses connect for SHIFT award applications.
  - Academic investigators describe product-oriented research topics
  - Businesses describe their diseases and products
  - Networking sponsors provide network contact information

Links to More Information

Email Alerts and Funding News
http://funding.niaid.nih.gov/researchfunding/newsletter/pages/subscribe.aspx

Advice on SBIR and STTR Applications
http://funding.niaid.nih.gov/researchfunding/sb/pages/pres.aspx

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