



SBIR/STTR; an Industry Gateway to Additional Non- Dilutive Funding

FreeMind Group Webinar

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July 10th, 2012

FreeMind
Group, LLC

Join us every Tuesday at Noon EDT for
the weekly FreeMind educational
webinar.

Syllabus:

- 1.SBIR/STTR
- 2.Details of a Detailed **Budget**
- 3.Joint webinar with the **Michael J. Fox Foundation** on Parkinson's and other Neurological disorders
- 4.**BARDA** – mission and current funding opportunities
- 5.**Medical Devices** funding opportunities
- 6.**Oncology**
- 7.**DOD** – DARPA, DTRA, US Army, etc.
- 8.Industry Academic **Partnership programs**
- 9.Bio Imaging and Bio engineering
- 10.**Biodefense** and infectious diseases, NIAID

Webinar program is
subject to change

FreeMind
Group, LLC

- ✓ Est. 1999
- ✓ 25 Fulltime Employees
- ✓ Academia & Industry Clientele
- ✓ Extensive experience in submitting and winning large scale applications
- ✓ Over \$1.5B in cumulative awards

A Tool to Max. Your Funding Potential

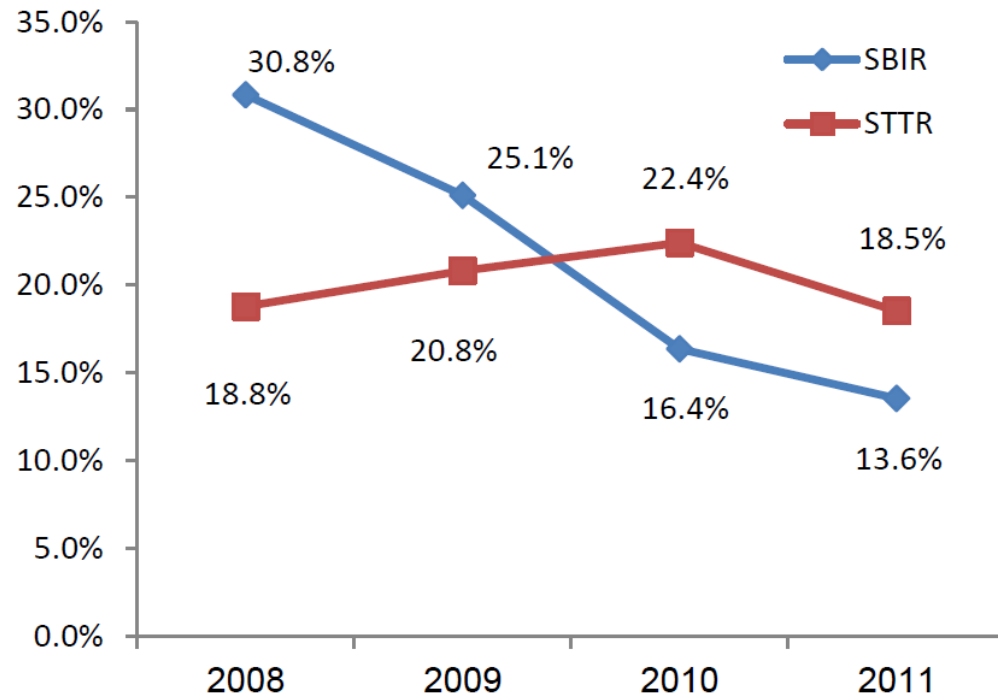
FreeMind
Group, LLC

- ✓ Identifying most relevant funding opportunities
- ✓ Strategize to max. application's chances
- ✓ Manage complex project production processes
- ✓ Lead joint application writing
- ✓ Supports final contract negotiations

Declining Success Rates

Steep decline in overall success rates for SBIR from 30% in 2008 to roughly 13% in 2011. STTR remains relatively constant

SBIR/STTR Overall Success Rates

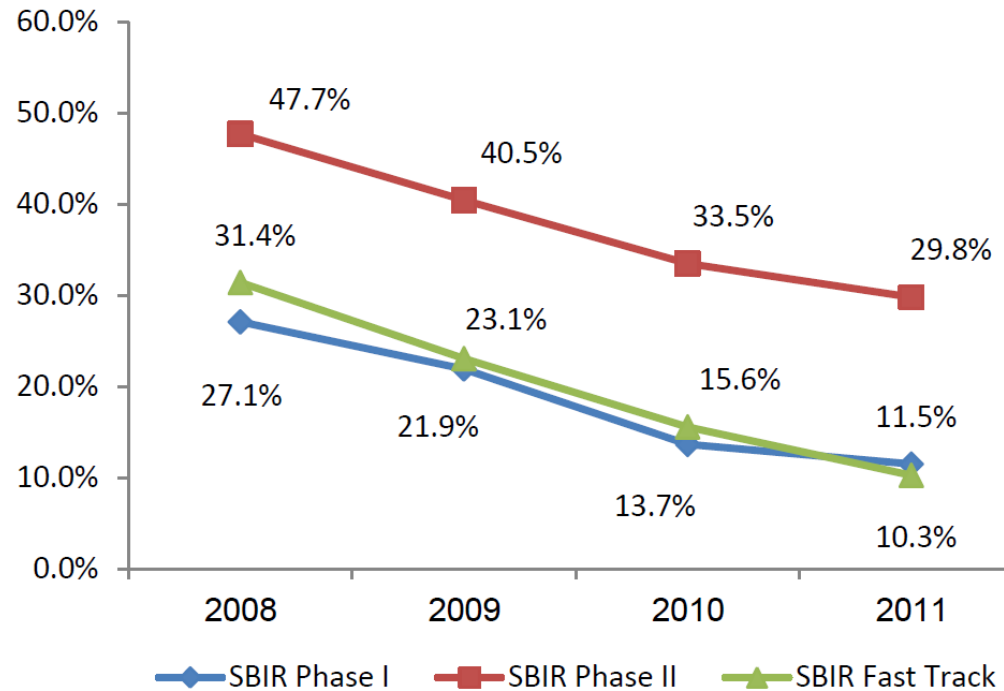


Adapted from the NIH Data Book, www.report.nih.gov

Phase
Breakdown

All Phases are affected by the decline in success rates.

SBIR Success Rates per Phase

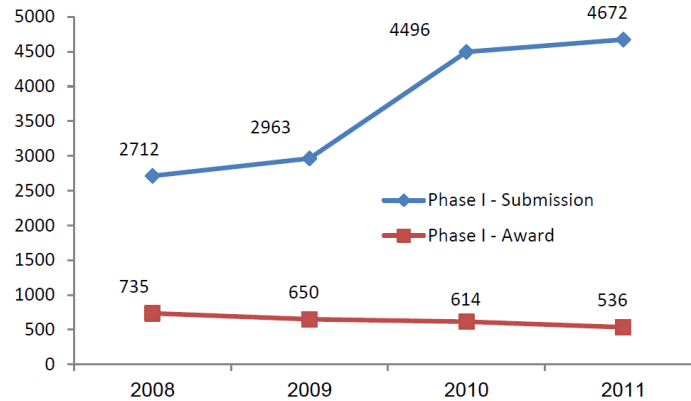


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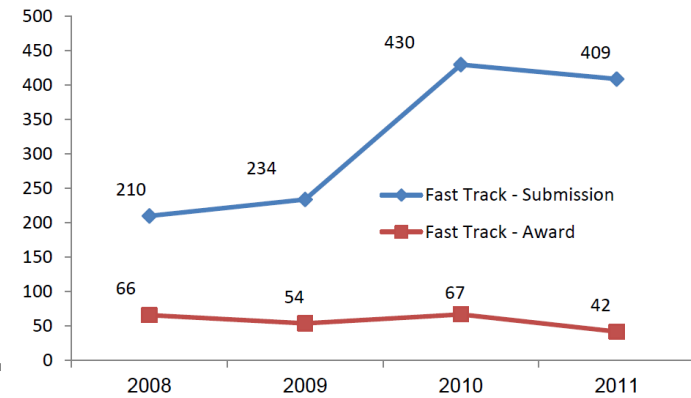
Some Interesting Statistics

Submissions vs. Awards

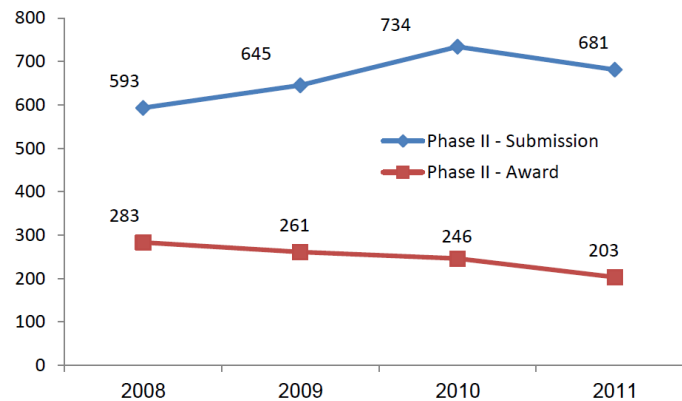
SBIR Phase I Submissions vs. Awards



SBIR Fast Track Submissions vs. Awards



SBIR Phase II Submissions vs. Awards



Record breaking number of submissions for all Phases together with fewer awards.

Phase I submissions rise 72% between 2008 and 2011!

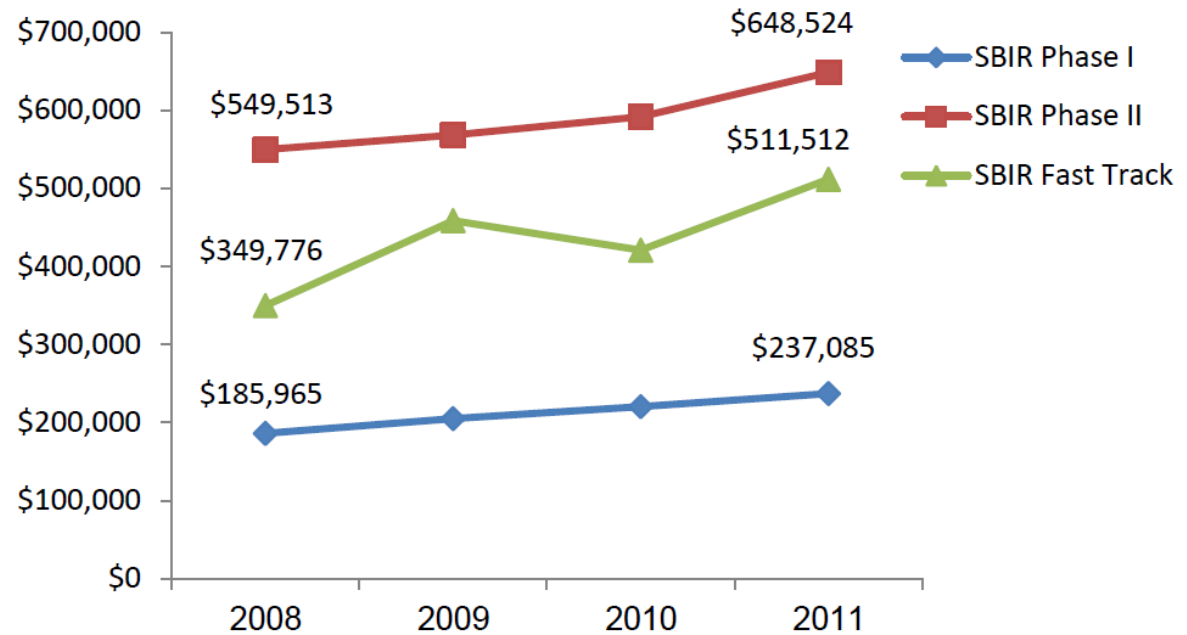
Adapted from the NIH Data Book, www.report.nih.gov

Some Interesting Statistics

The good news
(?)

Phase	% Increase 2008 -2011
Phase I	27%
Phase II	18%
Fast Track	46%

SBIR - Average Award by Phase



Adapted from the NIH Data Book, www.report.nih.gov

Some Interesting Statistics

Where is the money spent?

NIH Budget and allocation of funding remains relatively constant between 2009 and 2011

	2010	2011
Research Project Grant	\$16,598,000,000 (53%)	\$16,428,000,000 (53%)
Research Centers	\$3,026,000,000 (10%)	\$3,020,000,000 (10%)
R&D Contracts	\$3,459,000,000 (11%)	\$3,227,000,000 (11%)
Intramural Research	\$3,285,000,000 (11%)	\$3,269,000,000 (11%)

Adapted from the NIH Data Book, www.report.nih.gov

$$SBIR\ Percentage = \frac{\text{Total SBIR}}{\text{Total RPG}} = \frac{\$648,000,000}{\$16,428,000,000} \cdot 100 = 3.9\%$$

What about the remaining 96%? Are Companies Eligible? For most of it, YES!

SBIR/STTR

The STTR program is intended to:

Stimulate a partnership of ideas and technologies between innovative small businesses and non-profit research institutions. The STTR program assists the small business and research communities by commercializing innovative technologies.

The SBIR program is intended to meet the following goals:

Stimulate technological innovation in the private sector; Strengthen the role of small business in meeting Federal R&D needs; Foster and encourage participation by socially and economically disadvantaged small businesses and women-owned businesses; and improve the ROI from Federally-funded research for economic and social benefits to the Nation.

Phase I, II, III

Fast Track

----- Federally Funded -----

Phase I

To establish the technical/scientific merit and feasibility of the proposed R/R&D efforts. Budget guidelines: up to \$150K direct cost for SBIR (6 months), and \$150K for STTR (12 months).

Phase II

To continue the research or R&D efforts initiated in Phase I. Budget guidelines (2 years): up to \$1M direct cost for both SBIR and STTR.

----- Non-SBIR/STTR Funds -----

Phase III

To pursue with non-SBIR funds (either Federal or non-Federal) the commercialization objectives resulting from the results of the R/R&D funded in Phases I and II.

US based

Must meet eligibility criteria at the time of award!

Only US small businesses are eligible and must meet *all* of the following:

- Organized for profit, with a place of business located in the United States;
- At least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or
- At least 51 percent owned and controlled by another for-profit business concern that is at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the US; and;
- No more than 500 employees, including affiliates.

SBIR differs from STTR in two important aspects:

- The PI must have primary employment with the SBC
- SBIR encourages but does not require the SBC to partner with a research institution.

VC backed? Yes, and No.... Multiple VCs YES!, 1 VC, then No.

Routes

Investigator Initiated

- Establish interest within the NIH before submitting
- Highly focused – remember, NIH funds projects, not companies!
- Innovative
- Of great Significance to public health
- Can be completed on time and within Budget

Solicited route

- Addressing a specific scientific area
- Of innovative value and great significance to public health in said scientific area
- Can be completed on time and within Budget

Solicited

60 open solicitations in the SBIR/STTR Programs across the NIH!

Examples:

- Multiplex Assay Development for Arthritis and Musculoskeletal and Skin Diseases
- NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases
- New Technologies for Viral Hepatitis SBIR
- NINDS Exploratory Clinical Trials for Small Business
- Radiological/Nuclear Medical Countermeasure Product Development Program
- NeuroNEXT Small Business Innovation in Clinical Trials
- Development of novel and emerging technologies for the accurate detection and diagnosis of polymicrobial infections in biomedical laboratory animal models

Solicited

More Examples:

- Development of Appropriate Pediatric Formulations and Drug Delivery Systems SBIR
- NINDS Cooperative Program in Translational Research Small Business Awards
- Cancer Diagnostic and Therapeutic Agents Enabled by Nanotechnology
- Advanced Tools and Technologies for Deep Brain Stimulation
- Bioengineering Nanotechnology Initiative
- SHIFT Award: Small Businesses Helping Investigators to Fuel the Translation of Scientific Discoveries
- NIAID Advanced Technology SBIR
- Image-Guided Cancer Interventions

Solicited

Even More Examples:

- Optimization of Small Molecule Probes for the Nervous System
- Directed Stem Cell Differentiation for Cell-Based Therapies for Heart, Lung, and Blood Diseases
- Innovations in Biomedical Computational Science and Technology Initiative

And many more...

Unsolicited

Parent Announcements

(Parent **STTR** [R41/R42]) [PA-12-089](#)

- Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications

(Parent **SBIR** [R43/R44]) [PA-12-088](#)

- Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications

Challenges

- Overcoming limitations of the SBIR/STTR program – **virtual companies** (For SBIR, applicant must perform 67% in house in Phase I and at least 50% in Phase II. For STTR, 40% by Company and 30% by Academic collaborator)
- Product development driven – Milestones!
- Out of the ordinary sections – **Commercialization plan**, Consortium, multi PI etc.
- One consolidated coherent and responsive application

Risk
assessment



Key Issues

Systematic Approach

- Know the interests of the Agency
- Focus your project application
- Ask for what is necessary
- Present a complete project
- Leverage on research collaborations

Key Issues

Target the Right Mechanism

- Different “pockets of money”
- Different size of award/success rates
- Some projects will not have the right target
- Conduct a thorough strategic assessment

What Next?

SBIR/STTR is a great mechanism and is considered by many as a gateway to larger awards. We suggest submitting no less than 3 and upwards of 6 proposals per year thus increasing the likelihood for success.

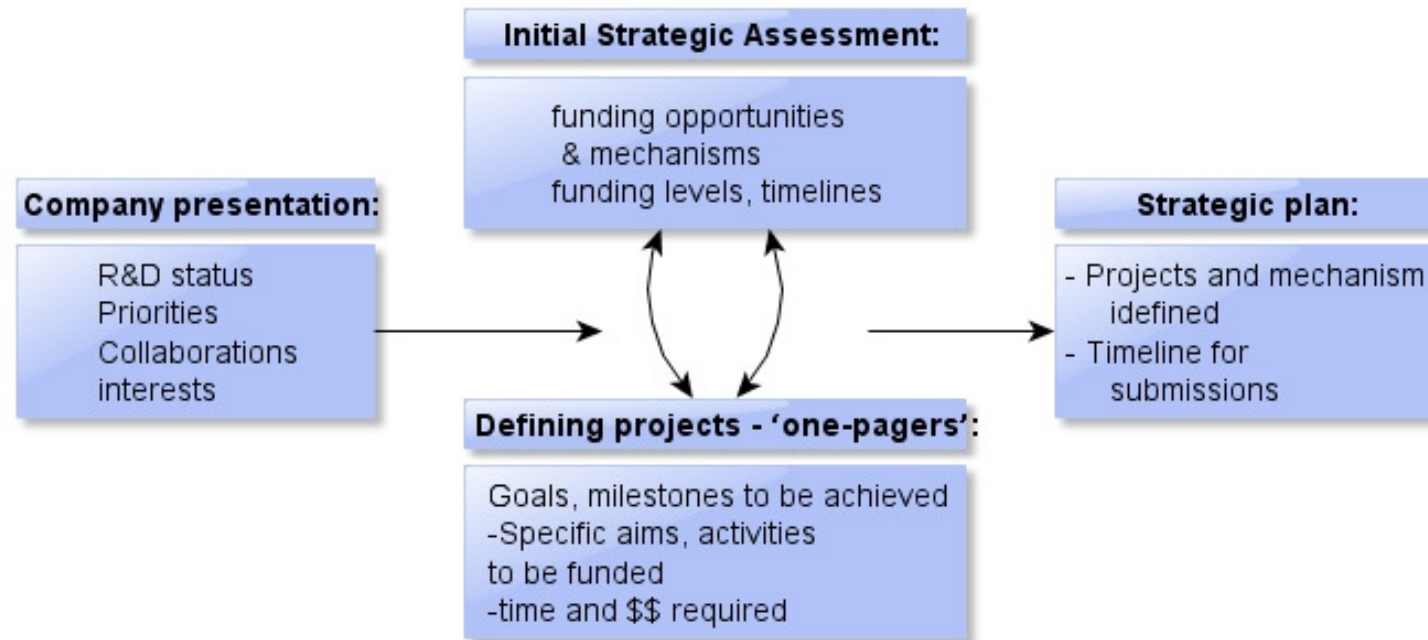
Despite being eligible and responsive, companies who have been successful with SBIR/STTR grants are oftentimes hesitant in their efforts to tap additional pockets of non-dilutive money (R01, R21, U01 etc.) and for all the wrong reasons.

To really take advantage of non-dilutive funding as a strategic source of funding we suggest companies submit SBIR/STTR work every cycle as well as additional proposals utilizing alternative mechanisms of action thus maximizing their non-dilutive funding potential

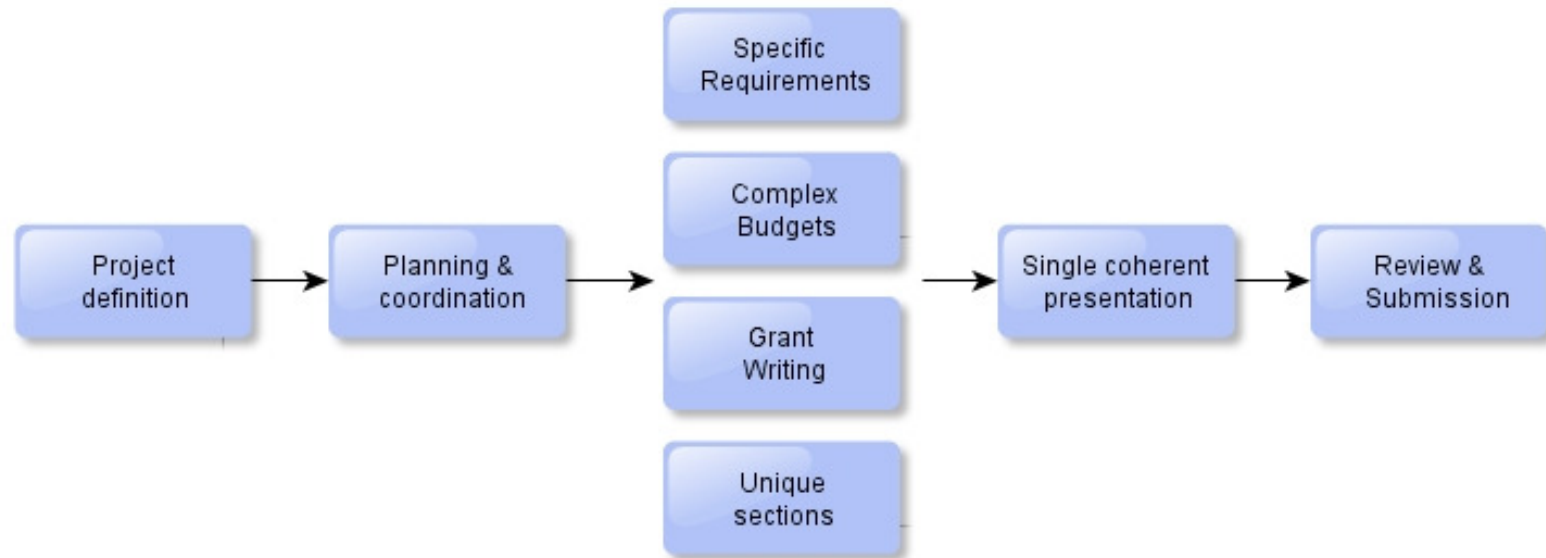
The Professional
Team

- ✓ 25 full time employees
 - ✓ Analysts
 - ✓ Managers/Writers
- ✓ Dr. Merav Geva, FreeMind's Director of the Professional Department & Chief Analyst

Strategic
Assessment



Specific Project



Thank you!

Contact Us!

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