





Secrets of NIH SBIR & STTR Grant Applications

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My Agenda Today

- Description of NIH small business programs (SBIR/STTR).
- Electronic grant application concerns.
- NIH FY2007 award data.
- NIH offers more than funds.
- Information on other NIH R&D funding opportunities.
- You should consider other federal agencies.







NIH SBIR and STTR Programs Fund About \$650M/Year

- **SBIR** – **S**mall **B**usiness **I**nnovation **R**esearch funds support research by business.
 - 2.5% of NIH extramural research budget.
 - Principal Investigator (PI) must be employed over 50% by company.
 - No minimum outsourcing (subcontracting) requirement.
 - Maximum outsourcing is 33% in Phase I and 50% in Phase II but is somewhat flexible.
- **STTR** – **S**mall **B**usiness **T**echnology **T**ransfer Research funds support collaborative research between company and U.S. research institution.
 - 0.3% of NIH extramural research budget.
 - Minimum outsourcing is 30% and maximum outsourcing is 60% and % is not flexible.
 - PI need not be employed by company.







Advantages

- **SBIR over STTR**
 - No research institution partner necessary.
 - More flexible percent effort than STTR.
 - Academic scientist consultant may earn consultant fees on top of salary.
- **STTR over SBIR**
 - Company may lack credible PI.
 - PI role essential to academic scientist.
 - Potentially better access to academic facilities, intellectual property and support.
 - Higher percent Phase I subcontract possible.
- **Select carefully** – changes not permitted from Phase I to Phase II.








SBIR and STTR Eligibility Requirements

- Awardee must be for-profit company.
- Principal place of business must be in U.S.
- ALL SBIR/STTR funded research must be conducted entirely in the U.S.
- Awardee must have over 50% ownership by U.S. individuals.
- Awardee must control research facilities where SBIR/STTR research will be conducted.
- Awardee must have 500 or fewer employees in the small business and all its affiliates.



NIH SBIR and STTR Are Three Phase Programs

- **Phase I**
 - Proof of feasibility
 - Funding for 1 year, sometimes 2 years
 - Median NIH award \$160K/year
- **Phase II**
 - Major research and development
 - Funding for 2 year, sometimes 3 years
 - Median NIH award \$375K/year
- **Fast-Track – Combined Phase I/II application**
- **Competing Phase II renewal**
 - For FDA related products
 - Compete with other Phase II applications
 - Award up to \$1M/year for 2 to 3 years
- **Phase III**
 - Remaining steps of commercialization
 - Not funded by government. Funded by other sources, e.g., angels, venture capital, etc.




Focus On Your Product, Not Your Technology



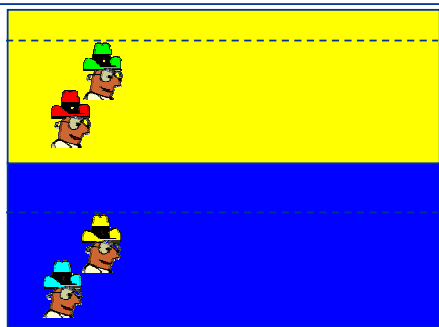
- Core technology builds a business.
- A single use of core technology builds an SBIR/STTR application.
- Advantages of focus on single use.
 - Meets needs of specific problem.
 - Targets committed reviewers.
 - Demonstrates business acuity.
 - Allows additional applications using same core technology.
 - Can prepare applications for more than one agency!
- Describe the public health and financial significance of your product.

NIH Program Announcements Funding Opportunity Announcements




- Program Announcements (PAs, now often called FOAs) are NIH staff "wish lists."
- Review committees usually evaluate an application responding to a PA no differently than any other application.
- You can handicap your application by trying to make it fit a PA.
- Respond to a PA only if the research you want to propose exactly matches the PA request.
- You do not need to respond to a PA to request an NIH Phase I award over \$100 thousand or a Phase I award for 2 years.


NIH Electronic Submission Roles and Responsibilities




FY2007 SBIR & STTR Applications



Type	Received	Funded	Award Rate
SBIR Phase I	3029	659	21.8%
No PA	2132	456	21.4%
PA	897	203	22.6%
STTR Phase I	995	128	12.9%
No PA	641	75	11.7%
PA	354	53	15.0%
FAST TRACK			
SBIR	230	40	17.4%
STTR	64	6	9.4%
SBIR Phase II	738	270	36.6%
STTR Phase II	145	36	24.8%



NIH Receipt, Review, and Award Dates



WAITLIST

SBIR

NIH Receipt, Review, and Award Dates

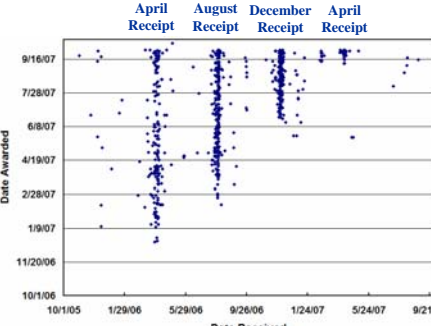
	Awards Within Payline		
	90%		10%
Receipt Dates	Apr 5	Aug 5	Dec 5
Initial Review	~Jul	~Nov	~Mar
Secondary Review	~Oct	~Feb	~Jun
Earliest Award	~Jan	~Mar	~Jun

Priority Score: 100 150 200 250 300 350 400

NIH Payline: YES (green) MAYBE (orange) NOT LIKELY (red)

Funding Probability

FY2007 NIH SBIR & STTR Phase I Receipt and Award




April Receipt, August Receipt, December Receipt, April Receipt

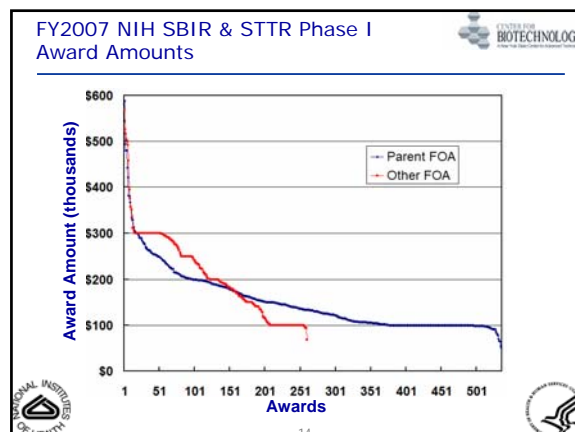
Date Awarded: 9/16/07, 7/28/07, 6/8/07, 4/19/07, 2/28/07, 1/9/07, 11/20/06, 10/1/06

Date Received: 10/1/05, 1/29/06, 5/29/06, 9/26/06, 1/24/07, 5/24/07, 9/21/07

Revised FY2007 Phase I Applications Try, Try, Again!




Type	Received	Funded	Award Rate
SBIR All	3029	659	21.8%
Initial	2210	411	18.6%
1st revision	647	183	28.3%
2nd revision	172	65	37.8%
STTR All	995	128	12.9%
Initial	725	69	9.5%
1st revision	233	46	19.7%
2nd revision	37	13	35.1%




- ### NIH Offers More Than Funds
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- Material transfer agreements (MTA), licenses, and cooperative research and development agreements (CRADA)
 - Pipeline to Partnerships (P2P) – partnership and licensing information <http://www.ott.nih.gov/p2p>
 - Collaboration opportunities and research partnerships (CORP) – partnership and services information <http://grants.nih.gov/grants/funding/corp.htm>
 - Technical assistance programs (TAP)
 - Market research assistance
 - Presentation assistance (dog & pony show)
 - Manufacturing assistance

- ### NIH SBIR Technical Assistance Program (TAP) – Competitive
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- <http://grants.nih.gov/grants/funding/tap.htm>
 - Niche Assessment Program (NAP) for NIH Phase I awardees
 - Market analyses of technology
 - Strategic planning for technology
 - Commercialization Assistance Program (CAP) for NIH Phase II awardees
 - Free 10 month program (except travel) to develop company's investor presentation
 - Presentation at venture forum
 - Pilot Manufacturing Assistance Program (MAP) for NIH Phase II awardees
 - Partnership with NIST Manufacturing Extension Partnership
 - Free 2-3 month program requiring minimum 100 hours of company time
 - Supports product movement from research to manufacturing

- ### Consider Other Award Activities
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- Small Grant Program (R03)
 - \$50K/year for up to 2 years.
 - Check participation by NIH Institute/Center.
 - Check Funding Opportunity Announcements.
 - Basic Research Grant (R01)
 - Exploratory/Developmental Grants Phase I (R21)
 - ~\$275K/2years.
 - Check Funding Opportunity Announcements, e.g., NIAID Microbicide Innovation Program.
 - Exploratory/Developmental Grants phase II (R33)
 - Only open to R21 recipients.
 - ~\$300K/year for up to 3 years.
 - Challenge Grant (RC1) \$1M (total cost)/18 months
 - Pros & Cons
 - No small business requirements.
 - Direct cost grants.
 - Open to academic investigators.
 - Compete with academic investigators.



Links to More Information


 DIVISION OF BIOTECHNOLOGY

Email Alerts and Funding News
http://www.niaid.nih.gov/ncn/newsletters/default_subscribe.htm

Narrated Animated Advice on SBIR and STTR Applications
<http://www.niaid.nih.gov/ncn/sbir/pres.htm>



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