

SBIR/STTR

A non-expert view

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Disclosures

- Microbial Imaging, Inc. – equity, IP
- Hydrocyanine Dyes – Licensing revenue (at some point in my life...maybe, maybe not)
- Cell Precision, LLC – equity and IP

A few Opening Thoughts

- Focus today primarily on NIH. All federal agencies support SBIR/STTR mechanism.
- NIH SBIR/STTR program is a set aside.
- Funding used to be easier, it is getting much more competitive.
- You need a business person
- After doing this, you will be forever grateful for what OSP does for you

More Thoughts

- It is a shorter timeline from application to funding (compared to RO1's)
 - Typically 6 months
- This is not a rapid process
 - Funding gaps between phases almost mandatory
- Lots of compliance issues
 - Animals, COI, etc.
- Start 4-6 months prior to submission deadline
- You need a CEO – usually not the faculty member but can be with permission

What is a Small Business Concern?

- It is a company....LLC and others OK
- Must be in US (<40% foreign owned)
- <500 employees
- Other rules apply
- ?? Special advantages to women and minority owned companies—not really
- Must be For Profit

Getting Ready to Apply

- Form a company – Guide on NIH Site
 - Legal Zoom etc. to set up a register your LLC
 - Dunn & Bradstreet number
 - IRS registration (EIN)
 - Approval from Emory SOM COI office
 - SAM registration
 - Registration at Grants.gov
 - ERA Commons registration
 - SBA registration

Good Info

SBIR.NIH.Gov

U.S. Department of Health & Human Services | National Institutes of Health

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NIH Small Business Innovation Research (SBIR) | Small Business Technology Transfer (STTR)

SBIR·STTR America's Seed Fund

Funding Opportunity Announcements (FOAs)

NIH's SBIR and an STTR Omnibus grant solicitations allow small businesses to submit researcher-initiated projects that are within NIH's mission. For the additional NIH SBIR/STTR FOAs, please view the Funding page.

SBIR Omnibus FOA (PA-15-269) | **STTR Omnibus FOA (PA-15-270)**

New to SBIR/STTR

Technical Assistance Programs | Funding | Electronic Submission Process | Success Stories | Contact Us | Engage and Connect

Alphabet Soup

- SBIR = Small Business Innovation Research
- STTR = Small Business Technology Transfer

SBIR vs STTR

SBIR

- Grant is to the small business concern
- Academic partner may get a subcontract
- PI must be employed by the small business
- The pot is bigger
- Minimum 67% of budget to small business in Phase I
- Minimum 50% of budget to small business Phase II

STTR

- Grant is to an academic institution
- Small business must get a subcontract
- PI can be employed at either the academic institution or the small business
- Minimum 30% of budget to academic partner and 40% to small business (phase I & II)

3 Phase System

- Phase I – Feasibility and Proof of Concept
- Phase II – Research and Development
- ~~Phase III - Commercialization~~

Phase I – R41/R43

- Feasibility and Proof of Concept
- Limited to \$150K total costs
 - 6 months for SBIR
 - 12 months STTR
 - Not really true
 - Can go over the cap for “approved topics” – no prior approval
 - SBIR’s end up with 12 month terms
- Strong preliminary data not required
 - Not really true
- Business Plan not Required
 - Must have a chance of being profitable

Phase I (Continued)

- For SBIR - 67% of the work (and the budget) must go to the small business
- For STTR – minimum of 30% to the academic partner, 40% to the small business (i.e., up to 60% to the academic partner)
- A lot of Phase I grants never transition to Phase II

Phase II (R42/R44)

- Research and Development
- Limited to \$1,000,000 total costs
 - Can go over the cap for “approved topics” – no prior approval required
- 2 year time period
- 12 pages
- Requires a good business plan
 - Formal, proscribed content, viable and critical
- Can have a Phase IIA and IIB
- Must have a good IP position

Phase II (Continued)

- SBIR – up to 50% of budget to academic partner
- STTR – same as phase I (30/40 minimum split)
- Additional equity a real plus
- The business team becomes much more important.

Variants

- Direct to Phase II
 - Requires equivalent of phase I data
 - SBIR only
- Fast Track
 - Phase I and Phase II Bundled
- Contracts – SBIR and STTR PA's
- Special Announcements
- DOD has very specific SBIR/STTR programs

Success Rates (NIH)

Submitted Funded Success
Rate

2015	SBIR	Fast Track	337	66	19.6%	\$18,157,545
2015	SBIR	Phase I	3,425	514	15.0%	\$117,110,555
2015	SBIR	Total Phase II	823	241	29.3%	\$179,946,727
2015	SBIR	Regular Phase II	442	163	36.9%	\$113,088,150
2015	SBIR	Direct Phase II	347	65	18.7%	\$55,150,363
2015	SBIR	Phase IIB	34	13	38.2%	\$11,708,214
2015	STTR	Fast Track	61	10	16.4%	\$2,171,909
2015	STTR	Phase I	911	149	16.4%	\$33,782,224
2015	STTR	Total Phase II	87	31	35.6%	\$21,597,183
2015	STTR	Regular Phase II	87	31	35.6%	\$21,597,183
2015	FY TOTAL		5,644	1,011	17.9%	\$372,766,143

Observations from NHLB SBIR/STTR Study Section

- The review panel has experts from industry and academia
- If it looks like a “R” grant, it will die
- Smoke and mirror companies are easily detected by the review panel
- You have to have a solid value proposition
- A strong academic leader is a positive
- Publications matter
- You are competing with “SBIR Factories”

More Observations

- Most funded grants are A1's
- Devices do not seem to do well lately
- Drugs seem to be doing better
- External validation from big companies and experts really helps (i.e., letters of support)
- No foreign subcontracts
- You are not Bill Gates, do not pretend to be
- Don't forget your day job

Pearls

- Indirect Cost Recovery
 - Set your own rate up to 40%
- “Fee” possible
 - A reasonable profit – maybe 7% or so of directs
- NIH will offer opportunities to other services
 - Market Analysis
 - Toxicology - SLOW
 - Synthesis – SLOW
 - Commercialization Readiness Pilot (CRP) Program
- SAM registration expires annually
 - Cottage industry out there to get you

Beware of “Death by SBIR”

A slow and painful process



Microbial Medical, Inc.

- Bacteria imaging agents
 - Targeted drug delivery
- Taylor, Murthy, Goodman and Wach co-founders
- Started with NIH Nanotechnology U01
- Boosted by GRA Phase IA, IB, II funding and a philanthropic gift
- SBIR Phase I x 2 (180K each)
- Phase II SBIR pending (\$1.6M)
- Angel Investors
- Lots of time and effort
- Expert Business Partners
 - Wach, Lowery, Martin