

Lessons Learned from Writing and Reviewing SBIR and STTR Federal Research Grants



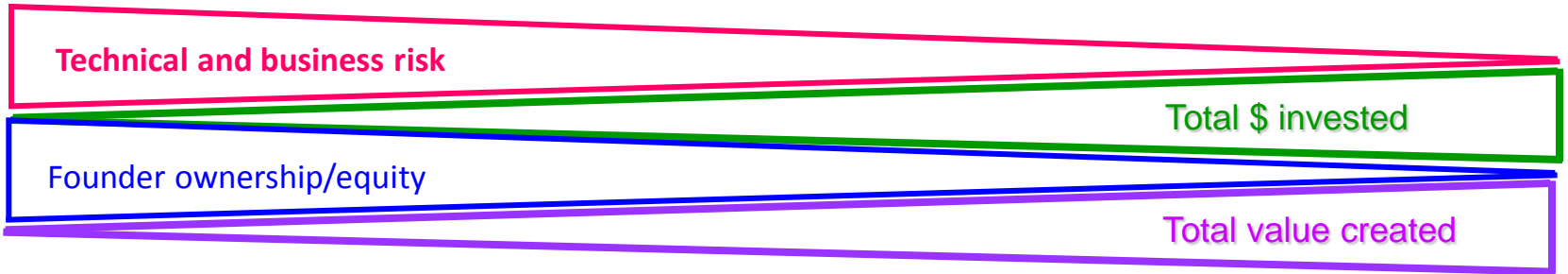
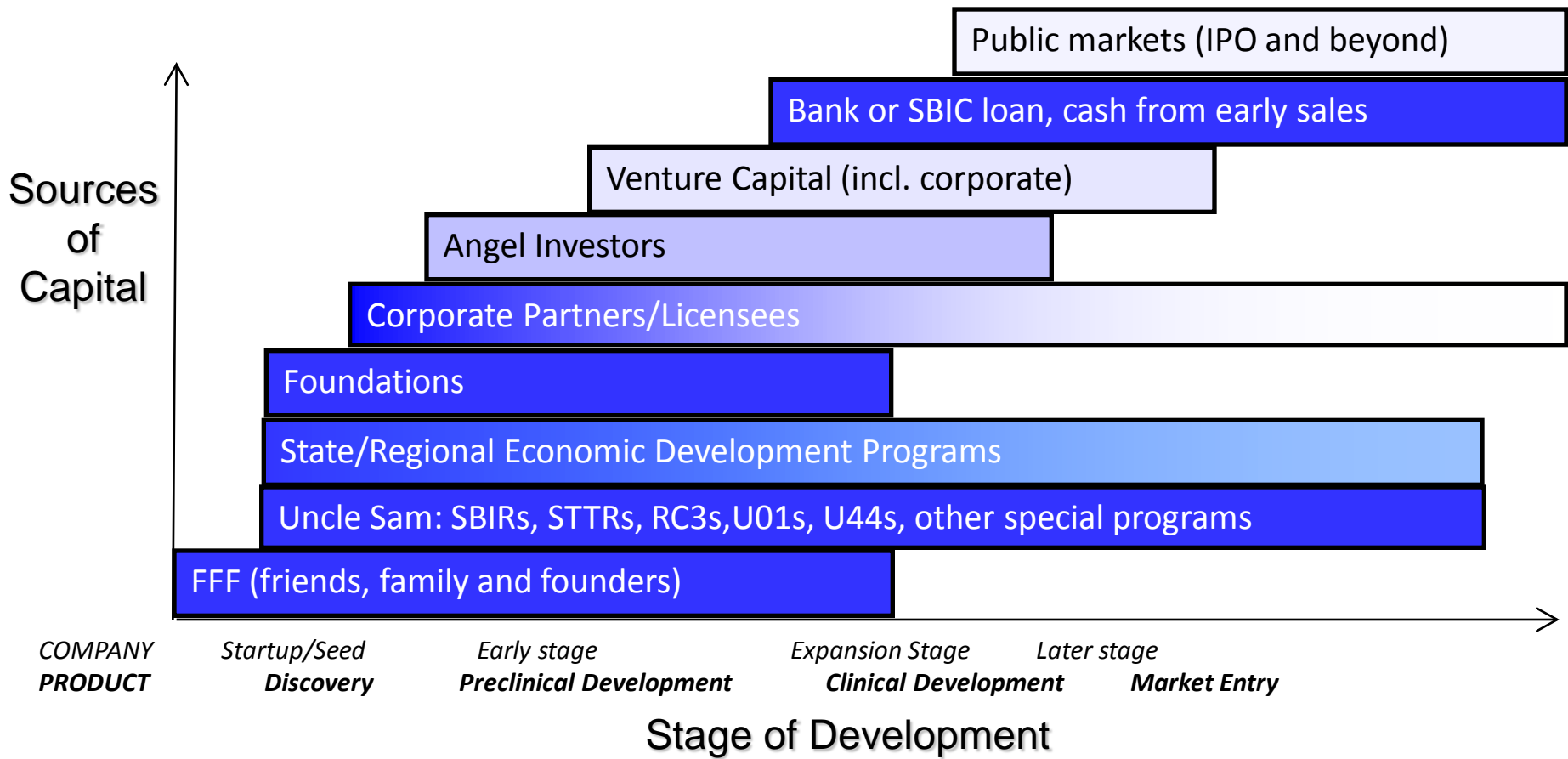
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Venture Cafe

1 Minute Summary

- In the beginning....should you apply?
- What do reviewers do?
- If you failed....understanding why (also useful to think about BEFORE you submit)
- Second chances...
- Jackpot!

SBIR/STTR Project Goal: Reduce Risk!





Focus!

- What product or service will the company offer?
- What will differentiate it from the competition?
- What innovation(s) will be required for commercial success?
- To whom will the company sell it?
- When is this going to happen?

REALITY CHECK: does SBIR project timing fit with business plan?

If you can't answer these questions, consider an RO1 to do basic research. Companies can submit RO1's, but their success rates are low and the output of the RO1 frequently does not generate the kind of information sought by corporate partners.

Is an Academic Inventor Involved?

Possible Roles in Translational Research

- Within a research institution
 - Company Founder
 - Scientific Advisory Board Member
 - Consultant
 - Contractor
 - Recipient of Sponsored Research
- Within a company
 - Entrepreneur (focus = fund-raising; not usually a good match)
 - Chief Scientific Officer (focus = innovation, applied/developmental science)

Is an Academic Inventor Involved?

Possible Roles on Small Business Grants

- Contact PI on an SBIR (must be >50% employee during project)
- Collaborator and non-contact PI on a multiple PI SBIR
- Collaborator and contact PI on STTR
- Consultant
- Subcontractor (if their institution allows it)

What kind of technology do you have?

- Are you working on a platform technology?
- Where are you in your product development plan (PDP)?
- How will the government view your technology readiness? (They have boxes for everything...) And what will they expect?
- What kind of progress can you make with SBIR \$\$?
- Go/No Go A to Go/No-Go B? Later in the PDP?

Is Uncle Sam the Right Investor?

- Typical angel or VC wants to hear
 - Little/no risk/problems
 - Only \$\$ required for success



- Uncle Sam won't pay unless SB

- Identifies the technical barrier preventing commercialization
- Describes **innovative research** that it will perform to overcome that barrier
- Defines what will be measured and how good it must be to prove that the barrier has been overcome





Choose the right agency

- **Platform Technology**
 - Can be used to create an impressive business plan
 - **INAPPROPRIATE** for NIH SBIR/STTR applications
 - **PREFERRED** for NSF SBIR/STTR applications
- **Individual Product or Service**
 - **PREFERRED** for NIH SBIR/STTR applications
 - Focus: data needed to advance product/service toward the market, and methods employed to collect those data (innovative research!)
 - **For investigator-defined projects:** target funding agencies with missions and interests relevant to the proposed product
 - **For agency-defined projects:** respond to program needs – especially true for DoD (has a significant number of life sciences related needs)

Talk (and Listen) to Funding Agency(ies)

- Have you been scooped? Search keywords on
 - <http://projectreporter.nih.gov/reporter.cfm> (NIH)
 - <https://www.fastlane.nsf.gov/a6/A6Start.htm> (NSF)
- Check interest areas (see agency websites for details)
- E-mail and/or telephone conversations with target agencies are highly recommended – but **be well prepared** and don't waste their time
- Check for relevant special programs on agency websites and in discussion with program officials
- For NIH, request multi-institute assignments in your cover letter to maximize likelihood of funding

What's the Intellectual Property Status?

- Is the required IP available? Protected?
 - Is 3rd party IP needed (freedom to operate?)
 - **DO NOT** submit a grant application unless/until you have filed at least a provisional patent
- Are licensor and collaborator IP issues defined?
 - Inventorship and ownership/**control** of new IP developed or reduced to practice (see Model STTR Agreement on NIH website)
 - Responsibility for filing and supporting new IP
 - Time for review before public disclosure and/or publication
 - If you are licensing IP, **INSIST** that the patent be filed before you submit the grant





Reality Check: Cash vs. Cash Flow?

Cash

- The goal of the Phase I grant (\$150K - \$225K over 6 - 12 mos) is to get Phase II funding (\$1M – \$1.5M over 2-3 yrs)
- Writing successful grants takes 150 – 450 hours
- SBIR funding never covers the entire project cost, especially in Phase I!

Cash Flow

- ≥6 months from submission to earliest funding date (more typically 9-12 months; even longer with resubmissions)
- ≥6 month gap between end of Phase I and funding for Phase II (Exceptions: extended Phase I with success criteria met in Year 1; FastTrack award; Phase “IA” or other gap funding award)



BEFORE You Start Writing: Final Reality Check

- Good match with company strategy and timeline?
- Commercial potential: Marketable product or service?
- Clear commercialization strategy; competitive advantages to drive acceptance by relevant market segment?
- Credible PI (& collaborators) with required expertise?
- Facilities, equipment, resources, established methods?
- Finances: adequacy of proposed budget
- Can describe technology/proposed research strategy without compromising IP/competitive position
- Enough time/resources to prepare competitive proposal?
- Good match with interests of target agency?

Words to the Wise



- Don't wait until the last minute!
- Start by registering (can take 3-6 wks)
- Allocate 2 full weeks for first complete draft
- Write it at least 2 mos before the deadline.
- An average Phase I takes **at least 150 hours** to complete (even if you already have a detailed plan).
- Give the full draft to some really anal(ytical) folks and get back their comments
- Get reads from both experts and non-experts
- Incorporate/rewrite based on their comments

Put On Your Reviewer Hat

(and Get at Least One “Outsider” to Do the Same)

GOAL

Clear and compelling presentation **intelligible to a BIMODAL AUDIENCE!!**

- **Teach** non-experts enough to understand that the problem is important and your approach is valid
- **Sell** the experts on your understanding of the field, the appropriateness of your scientific plan of attack, and your team’s competence to carry out the plan

The Review

- Process is different for each agency
- Many items in common
- Timing is different

Common Ingredients of Successful Applications

- Eligible, well-qualified small business
- Innovative approach to a commercial problem
- Proposed product/service with high market potential
- Research strategy with high technical merit and objective, quantifiable feasibility criteria/measures of success
- Novel hypothesis and/or significant need being addressed

Common Ingredients of Successful Applications - 2

- Program goals matched to target funding agency
- Focused work plan compatible with budget and timelines for the program
- Clearly defined rationale for scientific goals
- Clearly defined experimental strategy and endpoints
- Propose clear objective, quantitative measurements demonstrating advance from Go/No Go point A to Go/No Go point B

Review Criteria - NIH

PHASE I

- **Significance:** Important problem? Substantial commercial potential?
- **Investigator(s):** PI and team with appropriate expertise and experience?
- **Innovation:** Novel concepts/approaches? Original/Innovative Aims?
- **Approach:** Design and methods well-developed and appropriate? Potential problems identified/addressed?

Clear statement of technical barrier preventing progress toward commercialization and objective metrics to demonstrate that the barrier has been overcome (FEASIBILITY)

- **Environment:** All necessary facilities and equipment available? Scientific environment that contributes to the probability of success?
- ⇒ **Overall Impact:** Strengths/Weaknesses? Sustained impact?

PHASE II

All of the above + **Phase I feasibility criteria met?**
Credible Commercialization plan?
Letter(s) of support from potential commercialization partners

Review Criteria - NSF

- **Intellectual Merit**

1. Sound approach to establish technical & commercial feasibility?
2. Suggests and develops unique or ingenious concepts or applications?
3. Well qualified technical team?
4. Sufficient access to resources?
5. Reflects state-of-the-art? Advancements in state-of the-art likely?

- **Broader Impacts**

1. Commercial and societal benefits?
2. Marketable product or process relevant to NSF mission?
3. Team with appropriate balance of technical and business skills?
4. Prior commercialization success?
5. Competitive advantage vs. alternatives that address same market needs?
6. Enabling technologies for further innovation?
7. Likelihood of attracting further non-SBIR funding?

- **Commercialization Plan**

Company's strategic vision? Market opportunity? Company/team? Product features and benefits compared to the competition? Financing and revenue model?

Common Reasons for Poor Scores

- Lack of new or original ideas
- Ignorance of relevant published work
- Absence of an acceptable scientific rationale
- Diffuse, superficial, or unfocused research plan
- Questionable reasoning in experimental approach
- Lack of experience in the essential methodology
- Lack of sufficient experimental detail
- Unrealistically large amount of work

Common Reasons for Poor Scores - 2

- Lack of clear objectives, endpoints, criteria for success
- Inadequate statistical analysis
- Uncritical experimental approach, no discussion of potential pitfalls/ alternatives
- Uncertainty concerning future directions
- Poor case for commercial potential or societal impact
- *Failure to follow directions*
- *Assigned to the wrong institute or study section*

XYZs of Reviewerese

- Summary statement says X
- Reviewer probably said Y during the meeting
- You should do Z

Translations: Significance

- X: *“Low commercial potential”*
- Possible Y’ s:
 - I haven’ t a clue what these folks are trying to make
 - Nobody in his right mind would buy this
 - This is just a way for Dr. Consultant to get another postdoc, piece of equipment etc
 - This would be great for the three people in the world who have the syndrome
- Z: Clarify how your proposed product will reduce pain and suffering of the US populace. Societal significance/impact can outweigh lack of innovation!

Translations: Innovation

- X: *“Low level of OR no innovation”*
- Y: This is one of the dullest things I have ever read. There isn't a new idea anywhere.
- Z: Clarify why it is innovative OR clarify why it has high societal import

Translations: Approach

- X: Most common concern is lack of an objectively measurable feasibility statement or measure of success for the Phase I workplan
- Y: Generally as stated
- Z: Address each concern by listing it in the one page introduction to the amended application and specifying the pages where you have addressed it in the proposal. Add a statement, e.g. *“Feasibility will be demonstrated if at least 300 widgets can be made per hour at a cost of <\$0.35/widget with a fail rate less than 1%. ”*

Translations: Investigator

- X: *“Little/no experience in the area”*
- Y: The proposal sucks! No one who knew anything about it could have written this.
- Z: Rewrite.
 - Get outside help!
 - Adding a consultant to the team may help IF you assign a specific role/task to the consultant and justify the salary request on the budget justification page.



SciGro's Advice as of 2Q14

(post-reauthorization)

- Go for an SBIR instead of an STTR (where possible)
- Consider an NIH Fast Track **if** you have clear progression criteria
- Go for an NIH direct to Phase II **if** you have already performed work equal to that typically supported by a Phase I
- If not, go for a 1-2 year SBIR Phase I but **keep budget to <150% of guideline** amount
- Write a feasibility statement that says “Feasibility will be demonstrated if **“at least one** XYZ can be made/isolated/characterized...”
- Submit a Phase II application at the end of Year 1 of Phase I and keep your team working toward the 2nd (hopefully even better) XYZ while Phase II is under review.

Keep in mind as you write....



“There is no grantsmanship that will turn a bad idea into a good one, but there are many ways to disguise good one.”

*William Raub - Past Deputy
Director, NIH*



GOOD LUCK!!!