

Driving Innovation With Your Small Business: SBIR/STTR Funding

PRESENTED BY Jim Stefansic // Commercialization Consultant

MATERIAL PROVIDED IN PART BY Mark Henry // President Grow Emerging Companies, LLC **FUNDING PROVIDED IN PART BY:**







Jim Stefansic Commercialization Consultant

Co-founder of Pathfinder Therapeutics, Inc.

- Medical device startup out of Vanderbilt University
- Raised over \$14MM in venture capital as COO
- Served as PI on over \$3.5MM in SBIR funding
 - Survived "Valley(s) of Death"
 - Funding used to complete device platform & for clinical trials
- Company sold to Analogic after 10 years
- Education
 - PhD: Biomedical Engineering, Vanderbilt University
 - MBA: Belmont University
- Currently President & CEO of Raiven Healthcare







How do I Find Business Funding? 11Fs

- Fund it yourself
- Family
- Friends
- Former friends
- Fools
- Fraud
- Founders
- Financial capital from equity venture funds
- Financing through perceived future worth debt funding or loan
- Federal tax research credits (IRS Form 6765)
- Federal funding

What are SBIR & STTR Programs?

Small Business Innovation Research (SBIR) Program

Set-aside program for small business concerns to engage in Federal R&D – with potential for commercialization.

Small Business Technology Transfer (STTR) Program

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions – with potential for commercialization.



Agenda

- Basics of SBIR/STTR
 - Program overview, eligibility rules & key differences
 - Grants vs. contracts
 - Registration requirements
- Overview of proposal components & writing strategy
 - "5 Key Questions You Must Answer"
 - Quad Chart
 - Business Model Canvas
- Timelines & logistics coordination with statewide resources

You Will Leave This Session With:

- A thorough understanding of whether SBIR/STTR are a good opportunity for you/your firm
- Our insider advice that will save you time figuring it out yourself
- Tips to increase your chances of winning the award

- An understanding of this environment and the need for good ideas, good teams and good writing
- A head start on the learning curve for the SBIR/STTR proposalproduction process
- An action plan for preparing to write a Phase I SBIR/STTR Proposal

What is SBIR? STTR?

SBIR/STTR is the best opportunity for most small, high-tech firms to seek early-stage R&D funding.

"Small Business Innovation Development Act"

Congress established SBIR program in 1982; STTR in 1992 Renewed as part of S.2943, 2017 National Defense Authorization Act (NDAA) for 5 additional years (FY18 through FY22)

R&D money set aside for high-risk, high-payoff research conducted by small, for-profit firms.

Who Qualifies for SBIR/STTR?

SMALL BUSINESS

- 500 or fewer employees (including affiliates)
- For-profit
- Individual Ownership
 - Greater than 50% US-owned by individuals and independently operated OR
 - Greater than 50% owned and controlled by other business concern/s that is/are greater than 50% owned and controlled by one or more individuals OR
 - Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these

ALL WORK MUST BE PERFORMED IN UNITED STATES

PATENT RIGHTS GO TO SMALL FIRM; GOVERNMENT HAS LIMITED RIGHT TO USE



Three Phases of Proposal (Generally)



NEW REAUTHORIZATION: Direct to Phase II again available for NIH only (NOT-OD-19-019)



How Competitive is the Process?

PHASE I PROPOSALS THAT WIN FUNDING

PHASE II PROPOSALS
THAT WIN FUNDING

8-16%

40%

(appx. 1 in 6 to 1 in 12)

(appx. 2 in 5)

Technical merit and credibility are key criteria—but IMPACT gets more attention now, along with genuine commercial potential (I-Corps program)

Typically not price sensitive. Ask for the funding that you need & can justify.

What type of companies win?

First-time submitters to NSF

Were founded < 3 years prior to award for NSF

Had 1 to 5 employees

68%

59%

81%

KEY SBIR Program Rules

2/3 of Phase I work and 1/2 of Phase II "work" must be performed by the small business

"Work" is often measured by money spent (including indirect and fee) but with variations

Collaboration with academics, other firms, national labs allowed but not required (which differentiates SBIR from STTR)

We encourage collaborations on nearly all projects to boost team credibility and capabilities Principal investigator (PI) must be primarily employed by firm during period of performance

51%, minimum, during period of performance (not necessarily based on full-time employment)

Time may be distributed over multiple projects, but 51% is employment status with the firm

Some agencies have **minimum PI time** on the project (20%)

Phase I awards typically \$70,000 to \$150,000 for a 6-9 month effort (\$225K+ possible)

Phase II awards typically \$400,000 to \$1,000,000 for a twoyear effort (\$1.5M+ possible)

Agencies may obtain waivers on above with justification. **Study each solicitation!**

Some agencies provide Phase I and Phase II supplements ("Phase IIb") to continue R&D and to initiate commercialization activities, especially FDA clearance (HHS)



KEY STTR Program Rules

0.45% of agency R&D set aside for STTR

Much smaller than SBIR, but win rates not necessarily lower

Agencies with over \$1B in extramural research budget (top five) must support STTR

Research institution collaboration is required

Minimum 40% budget to small business

Minimum 30% budget to partner research institution

PI employment requirements for STTR

DOD, NIH, DOE and NASA allow PI from non-profit

NSF requires PI employment at small business

Note that STTR is supposed to involve tech transfer from non-profit out to small firm—but expertise/research is often all that is provided

Project and money are still managed by the small firm, with subcontract to non-profit

STTR is a three-phase program that parallels the SBIR approach

Phase I awards are typically made for \$100,000 to \$225,000 for one year's work

Phase II awards are typically made for \$500,000 to \$1MM-plus for two years' work

"Phase III" to be funded by private or non-SBIR government money for commercialization, in addition to "Phase IIb" awards

Allocation of shared intellectual property rights typically is part of a subcontract agreement with the STTR non-profit partner(s)



SBIR/STTR Critical Differences

SBIR		STTR		
PARTNERING REQUIREMENT	Permits Partnering	Requires a non-profit research institution partner		
PRINCIPAL INVESTIGATOR	Primary Employment must be with the small business	PI may be employed by research institution OR small business		
WORK REQUIREMENT	GUIDELINES : may outsource up to 33% in Phase I, 50% in Phase II	REQUIRED: 40% small business; 30% research institution partner		
PROGRAM SIZE	3.2% (FY15- \$2.25B)	.45% (FY15 - \$296M)		
AGENCY PARTICIPATION	11 agencies (extramural R&D budget > \$100M)	5 agencies (extramural R&D budget > \$1B)		

Other SBIR/STTR Differences

- Solicitation differences among (and within) agencies
- Budget differences (agency size/level of funding)
- Grant agencies vs. contract agencies
- Various amounts awarded over different times
- Different pre-review/sorting processes and objectives
- Different review processes
- Various levels of interest in commercial potential
- Wide diversity in the topics and areas of interest as well as the projects funded

Recent Changes

Reathorization (2013-2017)

Venture Capital (VC) funded companies are eligible for SBIR but cannot be >50% owned by a single VC fund and awards are capped

Direct to Phase II Program was created then ELIMINATED BUT NOW REAUTHORIZED!

For any studies involving human subjects, review new rules and regulations on what defines a clinical trial



Agencies that participate in SBIR & STTR

TOTAL - \$2.5B • FY 2015

SBIR

Department of Agriculture (USDA)

Due dates per year: 1 • Budget: \$20.3M

Department of Commerce (DoC) NIST, NOAA

Due dates per year: 2 • Budget: \$8.4M

Department of Education (ED)

Due dates per year: 2 • Budget: \$7.5M

Department of Homeland Security (DHS)

Due dates per year: 2 • Budget: \$17.7M

Department of Transportation (DOT)

Due dates per year: 2 • Budget: \$7.9M

Environmental Protection Agency (EPA)

Due dates per year: 1 • Budget: \$4.2M

SBIR & STTR

Department of Defense (DoD)

Due dates per year: 3 • Budget: \$1.07B

Department of Energy (DOE)

Due dates per year: 2 • Budget: \$206M

Department of Health and Human Services (HHS)

Due dates per year: 3+ • Budget: \$797M

National Aeronautics and Space Admin (NASA)

Due dates per year: 1 • Budget: \$180M

National Science Foundation (NSF)

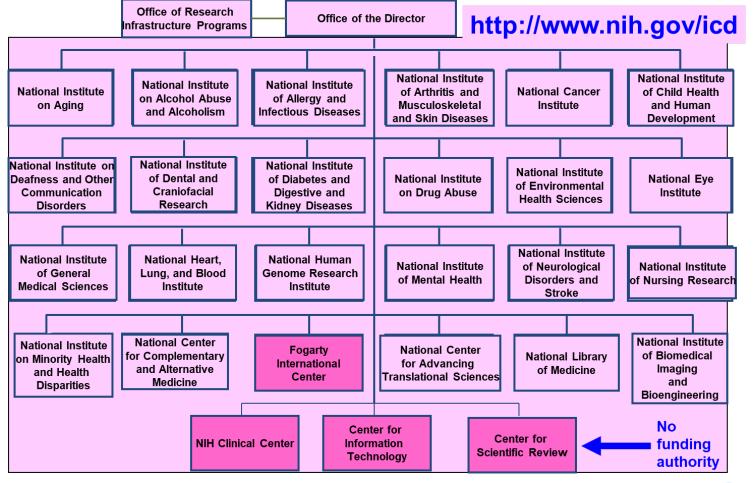
Due dates per year: 2 • Budget: \$176M



Grants







National Institute(s) of Health



NIH INSTITUTES AND CENTERS

National Cancer Institute (NCI)

National Eye Institute (NEI)

National Heart, Lung, and Blood Institute (NHLBI)

National Human Genome Research Institute (NHGRI)

National Institute on Aging (NIA)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

National Institute of Allergy and Infectious Diseases (NIAID)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

National Institute of Biomedical Imaging and Bioengineering (NIBIB

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

National Institute on Deafness and Other Communication Disorders (NIDCD)

National Institute of Dental and Craniofacial Research (NIDCR)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

National Institute of Environmental Health Sciences (NIEHS)

National Institute of General Medical Sciences (NIGMS)

National Institute of Mental Health (NIMH)

National Institute on Minority Health and Health Disparities (NIMHD)

National Institute of Neurological Disorders and Stroke (NINDS)

National Institute of Nursing Research (NINR)

National Library of Medicine (NLM)

NIH Clinical Center (CC)

Center for Information Technology (CIT)

Center for Scientific Review (CSR)

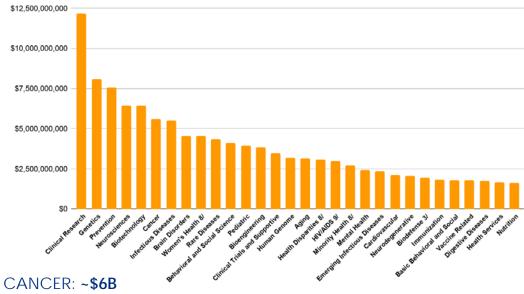
Fogarty International Center (FIC)

National Center for Advancing Translational Sciences (NCATS)

National Center for Complementary and Integrative Health (NCCIH)

SPENDING AT NIH

Top 30 Funded Categories



NEUROSCIENCES: ~\$6B

INFECTIOUS DISEASES: ~4\$B



SBIR/STTR Funding Agencies

Contract Agencies

(mission agencies)

- Typically have narrow topics
- Have a specific problem or need
- You must grasp & respond to that need
- Reviewed internally

"Focus on what we asked for, not what you think we need."

--Susan Nichols, DARPA SBIR Program Mgr

Grants - 40%

(your idea)

- Want to support good ideas
- Typically very broad topics
- Reviewed by a third-party



Contract & Grant awards

Grants

Department of Agriculture (USDA)

National Science Foundation (NSF)

Department of Energy (DOE)

Department of Health and Human Services (HHS) (NIH, CDC, FDA, ACF)

Department of Education (ED) (National Institute on Disability and Rehabilitation Research)

Contracts

Department of Commerce (DoC) (NIST, NOAA)

Department of Defense (DoD)

Department of Homeland Security (DHS)

Department of Transportation (DOT)

National Aeronautics and Space Admin (NASA)

Department of Education (ED) (Institute of Education Services)

Department of Health and Human Services (HHS) (NIH & CDC only)



SBIR/STTR Initial Registration

Standard Registration items for all agencies

- **EIN** Employer Identification Number
- **DUNS number** 9-digit code for each physical location of business
- System for Award Management (SAM) federal procurement system
- SBA's Company Registry Database SBC control id

DoD does not require SAM registration until time of award but encourage applicants to get it when submitting.

SAM registration is not required before the SBIR.gov registration.

Checklist for requirements - Appendix B

NOTE for NIH Applications

NO MORE ADOBE FORMS USE ASSIST.

Downloadable form option retired

Jan 1, 2018

Grants.gov no longer provides an option to download application package

Grants.gov no longer processes application packages previously downloaded



SBIR/STTR Registration Requirements

	NASA	HHS	NSF	DOE	DOD
DUNS number	X	X	X	X	X
SAM.gov	X	X	x	X	X
SBIR.gov [company registry]	X	x	x	X	X
Grants.gov		X	x	x	
eRA Commons		x			
Electronic Handbook (EHB)	X				
NSF FastLane			x		
DOE Portfolio Analysis and Management System (PAMS)				X	
fedconnect.net (Federal government acquisition & grant portal)				x	
Funding Accountability and Transparency Act Sub-award Reporting System				X	
DoD Submission Website (dodsbir.gov)					X

Overview of Proposal Content

Typical Proposal Content

- Cover Letter
- Abstract/summary and potential benefits
- Identification of problem / opportunity (including assessing state of the art)
- Technical objectives
- Research plan
- Related work
- Relationship to future research or R&D

- Commercialization strategy
- PI, key personnel, subcontractors, consultants
- Facilities, resources, and equipment
- Prior, current, or pending awards
- Cost proposal and budget justification
- Letters
- Subcontractor (e.g., STTR) agreements



Five questions you must answer

- Will your team make the major commitment necessary to win?
- Do you have a great research or R&D idea?
- #3 Does the government funding timeline make sense for your R&D needs and for your needs?

#4 Can your team prove its credibility in this highly competitive arena?

Do the Phase I and Phase II budgets and scopes of work make sense for your R&D needs?

#1 Level of Commitment

Developing a competitive proposal can take hundreds of hours. A Phase I SBIR typically requires between 100 and 300 person-hours.

- Are you willing and able to commit the required hours and funds to develop the proposal?
- Do you have a champion for this proposal project?
- Is the rest of your team willing to do what is necessary? Do they understand what they need to do, and when? Can you count on them to perform?



Your proposal champion must be willing to do anything to win!



#2 Viability

What is the "great" idea? Is it really research? Is it really new and potentially valuable?

Is the idea genuinely novel?
Can you prove it? Do you know the state of the art?

Does the concept have a market? What is it? How do you know? How long will it last?

Who in the federal government would care? How do you know?

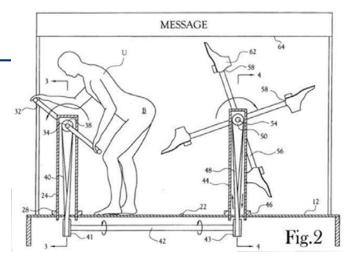
Are you an inventor or an entrepreneur? Is the idea just an invention or the basis for a successful business?

Is the idea consistent with your business plan/model?

Does it meet the stated criteria in the SBIR/STTR solicitation?

What kind of competition do you have?

(If you really believe you have no competition, go directly to jail, do not pass "Go," and do not collect \$200....)



Just because you have a patent doesn't make something valuable.

"User-operated amusement apparatus for kicking the user's buttocks"

Joe W. Armstrong (Lenoir City, TN) US 6,293,874 (Sep. 25, 2001)



#2 Viability Are You Ready To Start The Award Process?

For R&D Projects

- Has work begun ("preliminary data")?
 What R&D remains?
 Do key feasibility issues remain?
- Is the idea already patented and is that a good thing or a bad thing?
- Why does the idea still need seed money, and why do the Feds need to provide it?
- How will you sell the idea as an R&D project?
 Will it STILL be an R&D project when it is funded?

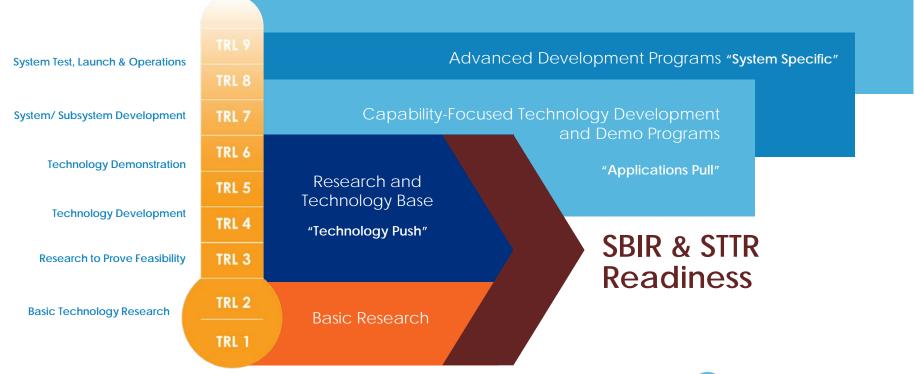
For Development Projects

 Is the current stage of development ideal for the solicitation's intent? Is the "Technology Readiness Level" (TRL) appropriate (if applicable)?



#2 Viability

SBIR & STTR Technology Readiness Levels





#3 Timeline and planning

Have you mapped out a realistic development and commercialization timeline for your product/service?

How does that timeline align with the typical government funding cycle?

What IS the typical funding cycle for the process you are pursuing?

The government process is slow and imperfect, but what are your real alternatives??

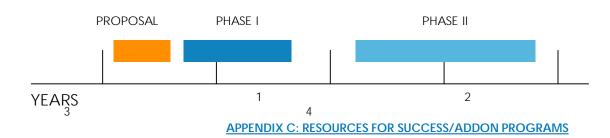
The SBIR/STTR Phase I/Phase II completion timeline is 3-5 years (best case).

Can your company survive during this time?

Will the marketplace for the idea survive this timeline?

Who is the competition?

How are they funded? Where will they be after 3 to 5 years?





#4 Establish Credibility

Who is your Principal Investigator (PI)?

- Is the PI an expert in the application area?
- Does the PI have appropriate academic, industrial, and other credentials? Publications? Projectmanagement experience?
- Is the PI eligible/available for the particular program?
 (For SBIR, it's 51% employed by the small firm during the project. Check each agency solicitation for the specific basis being used and for PI minimum commitments to the projects.)

Is the right team in place? Collaborators? Are the state of the art and other key players known?

Does the company (or do the team members) have a proven track record of commercializing technology-based products? SHOW, don't just tell.

Are the necessary facilities/equipment available? Do you have proof?

Has related work been completed?

Does compelling preliminary data exist (produced by you and/or others)?

APPENDIX D: ESTABLISH CREDIBILITY BEFORE YOU WRITE



#5 Budget Alignment

- Review RFP thoroughly before writing
- When you start writing also start your budget because your budget needs to match your scope of work
- Follow the rules
- Make sure you have a balance of direct, indirect, and fee that allows you to run your business
- Provide a complete budget narrative and justification
- Make sure you understand the difference between direct costs, indirect costs and fee

Make sure the direct costs component of your budget i consistent with the work proposed.

No one will be impressed if you try and complete 2x the work for the budget proposed. They will instead assume you don't understand the costs associated with the work and that you can't properly manage the project.





"Getting Ready to Write"
Mark Henry // President
Grow Emerging Companies, LLC



Mark Henry has three decades of federal funding experience and developed/managed the proposal process at Bend Research, Inc.

He won 175 of 350 SBIR proposals at Bend

Identify and articulate a significant unmet need (or unfulfilled opportunity) **with high potential IMPACT** — including what is wrong with the current state of the art

Describe your novel approach to solving the problem or pursuing the opportunity (based on compelling preliminary data), **including team qualifications** and the key technical/economic feasibility issues and the research questions and success metrics.

Describe how Phase I sets up a follow-on Phase II project and leads into Phase III commercialization, including the major potential national impact



Set the stage - Identify and Quantify the Problem or Opportunity AND SET UP YOUR INNOVATION

- Get the audience interested at the outset (highlight the agency/national problem or opportunity)
- Identify and substantiate the importance of the problem the need (If the reviewers don't buy into the need or significance, the proposal is dead.)
- Summarize the **state of the art and its shortcomings** (without shortcomings, there's no need for R&D....)
- Discuss why the problem has not yet been solved, given that it's so important. Describe the technical challenges to solving the problem and the potential benefits (the TECHNICAL challenges are what the R&D is about).



State the Theme - Your Solution

- Describe the concept of your solution, identify the innovation being pursued, and establish the credibility of your team — including PRELIMINARY DATA. Discuss potential advantages in terms of addressing the disadvantages you identified in Setting the Theme.
- Present what you will attempt to prove in Phase I
 (and indicate how you will know when you are
 successful i.e., present measurable goals); list
 the key technical/economic questions that
 have to be answered in Phase I

Create a Vision

- Discuss how Phase I success will set up Phase prototype/demonstration/validation.
- Discuss the overall plan for Phase II. What will the Phase II work involve? What will a prototype look like? How will you test the prototype? How will you get to the point in Phase II where the private sector will be convinced to step in and support Phase III?
- Envision the world with your solution in it ("Phase III"), including how you will finance Phase III.



Current/Future Opportunities

Dept. of Health & Human Services (NIH) – January 5th / April 5th / September 5th (grants)

SMALL BUSINESS INNOVATION RESEARCH (SBIR)

AND

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

GRANT APPLICATIONS

NIH, CDC, and FDA Program Descriptions and Research Topics

SUBMISSION DATES

APRIL 5, 2018, SEPTEMBER 5, 2018, JANUARY
7, 2019, AND APRIL 5, 2019
National Institutes of Health (SBIR and STTR)
Centers for Disease Control and Prevention (SBIR)
Food and Drug Administration (SBIR)



Current/Future Opportunities

AGENCY	OPENS	CLOSES				
Department of Agriculture	23 Jul. 2018	25 Oct. 2018				
Department of Commerce						
1. NIST	16 Jan. 2019	30 Apr. 2019				
2. NOAA	13 Nov. 2018	29 Jan. 2018				
Department of Defense: (solicitations typically p	posted at least 30 days prior to ope	ning)				
1. DoD 19.1	8 Jan 2019	6 Feb. 2019				
2. DoD 19.2	22 May 2019	20 Jun. 2019				
3. DoD 19.3	24 Sep. 2019	24 Oct. 2019				
Department of Education:						
1. contracts	7 Dec 2018	21 Jan. 2019				
2. grants	15 Jan. 2019	3 Mar. 2019				
Department of Energy	17 Aug. 2018	15 Oct. 2018				
Department of Energy	26 Nov 2018	04 Feb. 2019				
Dept of Health & Human Services (NIH, CI		0 1 1 CO. 2019				
1. PHS/NIH (grants)	26 Jan 2018	5 Apr. 2018				
2: 2 225/2 (granto)	2010	5 Sep. 2018				
		5 Jan. 2019				
2. PHS/NIH (contracts)	14 Aug. 2018	22 Oct. 2018				
Homeland Security 2018.1	14 Dec. 2018	17 Jan. 2019				
Department of Transportation 2016-1	17 Jan. 2019	20 Mar. 2019				
Environmental Protection Agency	13 Jun. 2018	31 Jul. 2018				
NASA	11 Jan. 2019	29 Mar. 2019				
NSF 2019.1	1 Nov. 2018	4 Dec. 2018				
2019.2	14 May. 2019	14 Jun. 2019				
NOTE: Housing & Urban Development has expressed interest, but currently has no SBIR program.						

APPENDIX E: Key Information Sources on SBIR/STTR



Closed Opportunities

Solicitation	Agency	Program	Release Date	Open Date	Due Date	Close Date 🔿
Fiscal Year (FY) 2019 Request for Applications (RFA)	USDA	SBIR	07/23/2018	07/23/2018	10/25/2018	10/25/2018
DoD 2018.C STTR Solicitation	DOD	STTR	08/24/2018	09/24/2018	10/24/2018	10/24/2018
DoD 2018.3 SBIR Solicitation	DOD	SBIR	08/24/2018	09/24/2018	10/24/2018	10/24/2018
NSF SBIR Phase I (July 2018)	NSF	SBIR	03/14/2018	03/14/2018	07/10/2018	07/10/2018
NSF STTR Phase I (July 2018)	NSF	STTR	03/14/2018	03/14/2018	07/10/2018	07/10/2018
DoD 2018.2 SBIR Solicitation	DOD	SBIR	04/20/2018	05/22/2018	06/20/2018	06/20/2018
DoD 2018.B STTR Solicitation	DOD	STTR	04/20/2018	05/22/2018	06/20/2018	06/20/2018
FY 2018 NIST SBIR Phase I Notice of Funding Opportunity (NOFO)	DOC	SBIR	01/18/2018	01/18/2018	04/04/2018	04/04/2018
FY18 DOT SBIR Solicitation	DOT	SBIR	01/17/2018	01/17/2018	03/20/2018	03/20/2018
NASA SBIR 2018 Program Solicitation	NASA	SBIR	01/11/2018	01/11/2018	03/09/2018	03/09/2018
NASA STTR 2018 Program Solicitation	NASA	STTR	01/11/2018	01/11/2018	03/09/2018	03/09/2018





Meeting with Program Managers: The Quad Chart

PRESENTED BY Jim Stefansic // Commercialization Consultant

FUNDING PROVIDED IN PART BY:



What is a Quad Chart and why do I need it?

- For SBIR purposes, a Quad Chart is a tool SBIR program managers use in their initial evaluation of an application
- "Quad" refers to the 4 parts of the chart
- The chart is a concise way to share information about your project and team
- One is required in order to register for one-on-one sessions with any agency program managers
- A high-quality quad chart will make a good impression on agency program managers from potential funding agencies

Quad Chart Considerations

LOGO HERE

Contact: E-mail: Location:

COMPANY NAME (IF APPLICABLE) AND OTHER DETAILS HERE

Website:

Technology Description & IP Position

- What is the product or service to be developed? What critical market will it address?
- How is it different and better than what already exists or is in the process of being researched and developed through federal funding?
- . What stage is the product/service at in the R&D process? Is the technology still preprototype?
- How would your research team use \$150,000 and a six-month project performance period to prove early-stage success of your research idea?
- Have you considered what form of intellectual property protection would be most appropriate for protecting your technology once it is commercial-ready and on the market? Forms of IP protection include patents, trade secrets, and copyrights
- . Have you conducted a preliminary patent search on USPTO.gov? Have you also run a keyword search for SBIR/STTR awards (which are pre-patent)?
- At what time during the course of your SBIR/STTR project do you plan to take action steps to protect your IP before it hits commercial market? Only a small portion of SBIR/STTR funding can be used to support legal/other services not permitted with the majority of these award

Need / Market Opportunity & Impact

- What kinds of conversations have you had with potential customers to learn about their needs that could potentially be addressed by your technology?
- What indications of support have you received from potential customers (such as conditional order letters, letters of interest as project partners/customers)?
- What kind of online market research have you done to explore the competition compared features/limitations of those technologies with your proposed technology?
- ased on your online research and direct communication with potential customers, how big is the problem?
- What is it currently costing them (in terms of time, cost, quality of life for end users) to address the problem?
- How much would your customer pay for your technology (per unit), conditional upon developing a market-ready product by the end of Phase II?
- What is the size of the potential customer market that you plan to dominate with your technology?
- Within the broad market space, who comprises your initial target market?
- Have you identified existing industry players who could license your product after Phase II?
- How will your commercial-ready technology measurably improve the lives of end users?

Company / Team & Business Model **Technology Development Milestones**

- . What quantifiable measures of success will your team accomplish in the Phase I project to prove early-stage project feasibility?
- What kinds of product testing will need to be completed after Phase I to prove that your product is ready for commercial market?
- . How will you work with customers throughout the project development process to obtain feedback on your technology that addresses specific needs?
- What key personnel roles do you currently have filled on your team?
- What kinds of project partners do you need to engage to gain access to specialized individual knowledge, facilities, and other resources?
- . What are the market research areas that you plan to target with agency-specific
- How does your project idea align with the mission and aims of your target funding
- Which market segment will be most feasible for your team to address initially?
- How do you plan to sell to customers after Phase II? Directly or via a licensing partner?

Biz Model Canvas





I-CORPs Programs & Business Model Canvas

PRESENTED BY Jim Stefansic // Commercialization Consultant

FUNDING PROVIDED IN PART BY:





What is I-CORPS?

- Leverages <u>NSF investments</u> in research lineage of previous support
- Small grants to focus on creating a commercialization roadmap
- Addresses the "Ditch of Death"
- Nimble funding **immediate assessment**
- Projects are team-based commercialization is team effort
- Process-oriented, Curriculum-focused

I-CORP at NIH (PA-19-029)

An intensive Entrepreneurial Immersion course for scientists

Program was originally designed by serial entrepreneur Steve Blank in partnership with the NSF.

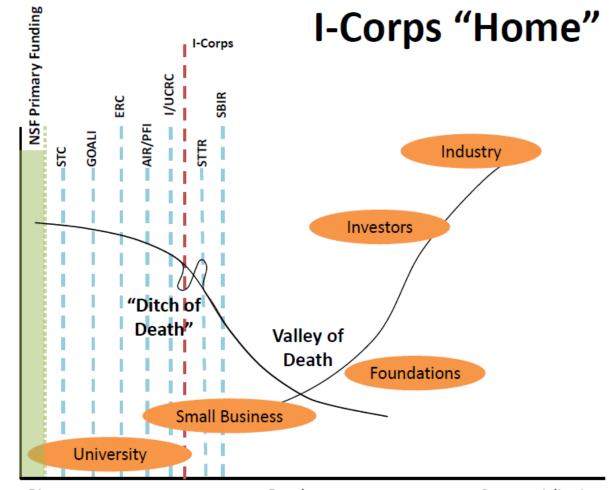
Over 600 academic teams have been through the program at NSF over the past 5 years.

NIH has worked closely with Blank and NSF to modify the program for life science startups.

Important goal of I-CORPs at NIH is to inform the Commercialization Plan.









Resources Invested

Plans vs. Planning

"In preparing for battle I have always found that plans are useless, but planning is indispensable."

Dwight Eisenhower



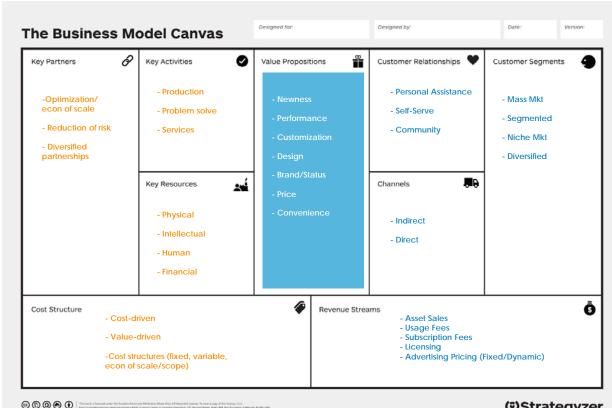
Business Model Canvas

Business Model Generation (Osterwalder & Pigneur)

- 1. Value Proposition (VP)
- 2. Customer Segments (CS)
- 3. Channels (CH)
- 4. Customer Relationships (CS)
- 5. Key Activities (KA)
- 6. Key Resources (KR)
- 7. Key Partnerships **(KP)**
- 8. Cost Structure (C\$)

DESIGNED BY: Strategyzer AG

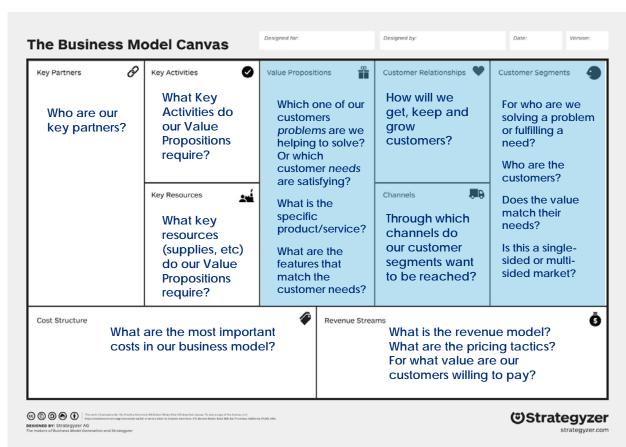
9. Revenue Streams (R\$)



strategyzer.com



Product Market Fit



Focus on the Value
Proposition and the Customer
Segments for your application.

Value Proposition

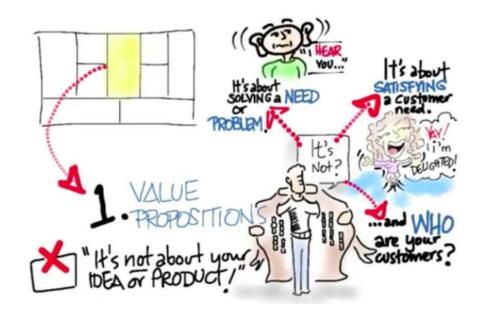
Is there a compelling need?

- Do you solve a problem?
- Do customers understand the problem?
- Do customers even care!?

A simple statement to help define the value proposition:

"X is a _____ [describe] company.

Through its _____ [feature(s)], it provides ____ [unique benefit(s)] to [target market]."



Most academic spinouts fail because they develop something no one cares about.



Customer Segments

Customer development is NOT sales!

Teams are not pitching their product or technology

Teams are listening to potential customers and other stakeholders and learning about:

- What customers want and need
- Pain points in their customers' daily routines
- Features of a technology that would provide value



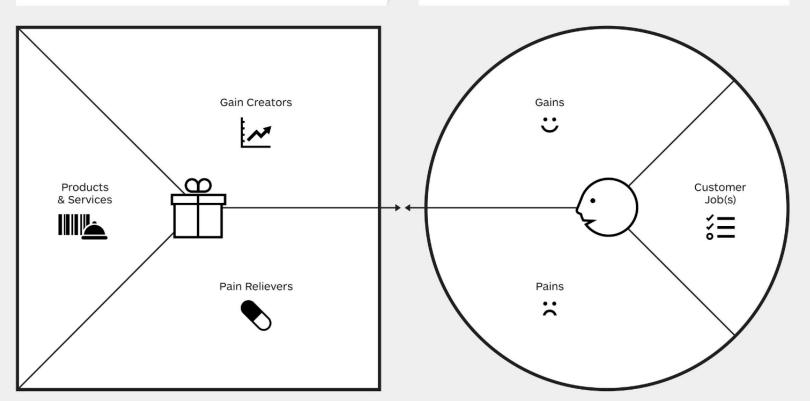


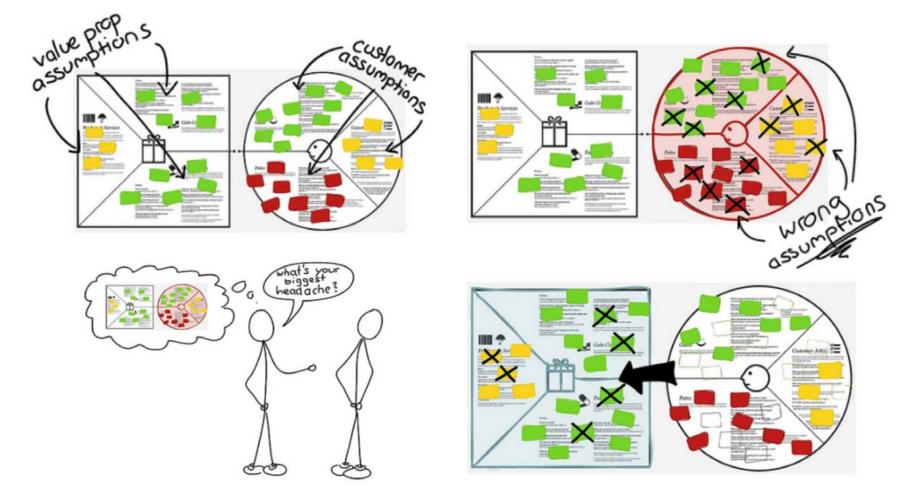
Now focus on the Value to the Customer

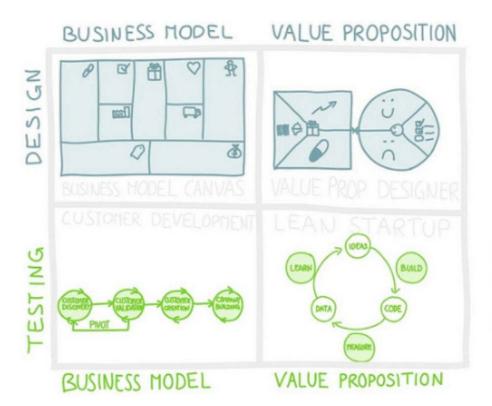


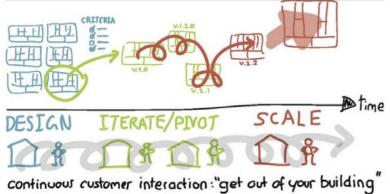
Value Proposition

Customer Segment









I-CORPs Case Study

Novoron: a new drug to restore function after spinal cord injury (SCI)

Before I-CORP

November 2012 - Dr. Travis Stiles' discovery published in Journal of Cell Science

August 2014 - PHASE I NIH grants awarded to develop drugs for SCI and stroke

Novoron at I-CORP

December 2014 - Novoron completes I-CORP at NIH

I-CORPs at NIH Learnings and Pivots

Low interest in early-stage SCI drugs ... but customer segments are interested in Multiple Sclerosis

After I-CORP

December 2015 - Novoron awarded NIH grant to **Evaluate New Treatments for Multiple Sclerosis** (MS)

- MS work led to increased interest in new indications
- Entered multiple strategic partnerships with focus on negotiation 1 deal

February 2016 - Xconomy recognizes Novoron as San Diego Life Science Startup to Watch in 2016

June 2016 - Patent Issued



Thank you!

Jim Stefansic, PhD MBA

Commercialization Consultant

jim.stefansic@gmail.com (615) 500-6798

Appendix

APPFNDIX A

Agency references/links

SBIR \$2.2 Billion

Department of Agriculture - https://nifa.usda.gov/grants

Department of Commerce

NOAA

Department of Defense

DoD SBIR/STTR Resource Center

Air Force

Army

Chemical and Biological Defense Program (CBD)

<u>Defense Advanced Research Projects Agency (DARPA)</u>

Defense Logistics Agency (DLA)

Defense Microelectronics Activity (DMEA)

Defense Technical Information Center (DTIC)

Defense Threat Reduction Agency (DTRA)

Missile Defense Agency (formerly BMDO)

National Geospatial-Intelligence Agency (NGA)

(formerly NIMA)

Navy

Special Operations Acquisition and Logistics Center

(SOCOM)

Department of Education

ED IES

ED OSERS / NIDDR

Department of Energy

Department of Health & Human Services (NIH, CDC, FDA, etc.)

Department of Homeland Security

DHS S&T Directorate
DHS DNDO

Department of Transportation

Environmental Protection Agency

National Aeronautics & Space Administration (NASA)

National Science Foundation

STTR \$300+ Million

Department of Defense

Air Force

<u>Army</u>

Defense Advanced Research Projects Agency (DARPA)

Missile Defense Agency (formerly BMDO)

Navy

Department of Energy

Department of Health & Human Services (NIH)

National Aeronautics & Space Administration (NASA)

National Science Foundation



APPENDIX B

Registration Information

	NASA	HHS	NSF	DOE	DOD
DUNS number	x	X	X	x	X
SAM.gov	x	x	X	x	X
SBIR.gov [company registry]	x	x	X	x	X
Grants.gov		x	X	x	
eRA Commons		x			
Electronic Handbook (EHB)	x				
NSF FastLane			X		
DOE Portfolio Analysis and Management System (PAMS)				x	
fedconnect.net (Federal government acquisition & grant portal)				x	
Funding Accountability and Transparency Act Sub-award Reporting System				x	
DoD Submission Website (dodsbir.gov)					X

Agency specific registrations and guidance

Department of Health & Human Services (NIH, CDC, FDA)

Grants.gov

eCommons (NIH online interface)

National Science Foundation

rasitane (Nor online interface)

National Aeronautics & Space Administration EHB (Electronic Handbook)

Department of Agriculture Department of Education Grants.gov

Department of Energy

Grants.gov

PAMS (DOE Office of Science Portfolio Analysis and Mamt. System)

ASAP (Automated Standard Application for Payments)

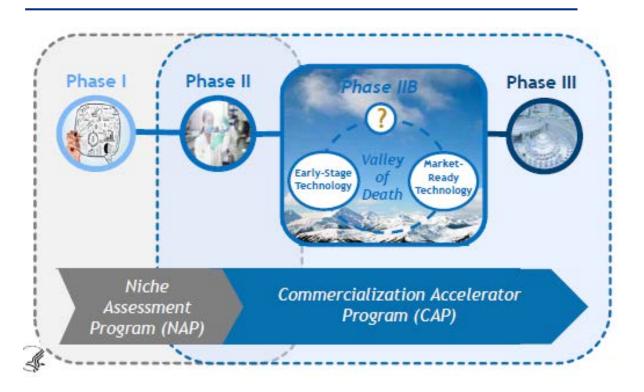
FedConnect (Federal government acquisition and grant portal)

Department of Defense



APPENDIX C

Timeline & Resources for Success



NAP – identify other uses of technology, market entry strategy

CAP – technical assistance, strategic alliances, investor partnership facilitation



APPENDIX D

Establish Credibility Before You Write

Team Members

- Principal Investigator
- Key Personnel
- Consultants
- Subcontractors
- Accounting

Background Information on Technical Area to be Proposed

Facilities and Equipment

These are where the work will be done (may be multiple locations) and the tools that are available in those facilities to support the work

Project Objectives

Your technology and how it addresses an important unmet problem A statement of your specific novel objectives for the Phase I project The results if your project is a success with emphasis on commercialization



APPENDIX E

Key Information Sources on SBIR/STTR

www.sbir.gov www.zynsys.com/sbir www.sbtc.org www.sbir.us/schedule.html (great schedule by agency chart)

Launch Tennessee SBIR/STTR resources:

http://launchtn.org/entrepreneurship/researchers/microgrants/

