NIH SBIR/STTR Commercialization Clinic: An Insider's Perspective

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CEO & Founder

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- **SBIR/STTR Programs Expert**
  - Managed programs across 24 NIH Institutes and Centers, the CDC and FDA on funding strategies, program development, contract management, advised NIH Director, briefed and testified in Congress
  - Presented at over 100 public conferences, SBIR workshops, trade organization conferences, Federal events
  - Launched 1st partnership with Biotechnology Industry Organization (BIO) Innovation Zone – showcased 55 SBIR awardees – due diligence on 100+ nominees, led selection process
  - Advised 1000's US small businesses on SBIR/STTR application strategies
- **Commercialization Strategy Advisor**
  - Managed NIH's flagship Commercialization Assistance Program – directed program framework and content development;
  - Evaluated over 800 business applications and selected over 380 SBIR/STTR awardees for CAP
  - Worked 1-on-1 with CAP companies on business plans, company management and growth strategies, fund-raising pitches, regulatory strategies, facilitated introductions, go-to-market roadmapping
  - Reviewed 15 State applications for SBA's FAST partnership grant program
- **Scientific and Technical Expertise**
  - Ph.D. in Neuroscience, Kent State University – role of cell-cell interactions in modulation of sleep cycles
  - Technology Transfer Certificate, NIH Foundation for Advanced Education in the Sciences – license agreement negotiations, biomedical business development, medical device product development, strategies for life sciences marketing
  - AAAS Science &Technology Fellow, NIH Office of Technology Transfer – licensing and market research

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disclaimer & terms

The opinions expressed herein do not represent the official views and positions of the Government agencies discussed, rather are those of bioPrime, LLC and its agents.

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Agenda for Today

8:30 – 9:30 am	SBIR/STTR Overview
9:30 – 9:45 am	Funding Opportunity Announcements
9:45 – 10:15 am	Technical Assistance Programs
10:15 – 10:35 am	Case Studies
10:35 – 10:45 am	BREAK
10:45 -11:10 am	Due Diligence
11:10 – 11:30 am	Review Process and Expectations
11:30 – 12:15 pm	LUNCH BREAK
12:15 – 1:15 pm	Specific Aims in-class exercise
1:15 - 1:25 pm	BREAK
1:25 – 2:15 pm	Scored Sections
2:20 – 3:20 pm	Commercialization Plan
3:20 – 4:00 pm	Discussion and Wrap-Up

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Program Assumptions

- Basic Understanding of SBIR and STTR Program structure, funding levels, Phase I and II objectives
- Objective 1: understand funding options and training resources for Phase II and later stage projects
- Objective 2: Commercialization Plan strategies
- Not a proposal writing workshop

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SBIR/STTR funding in your portfolio

Capital is in the form of *grants* and *contracts*

Strategic Investment in Innovation – ALMOST no strings attached!

$2.5 B Annually

Non-diluted seed funding:

- no repayment
- no debt service
- no equity forfeiture
- no IP forfeiture

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11 Federal Departments

Congressionally mandated set-aside budgets for SBIR = 3.2% and STTR = 0.45%

SBIR	STTR	Grant/ Contract	Total Budget FY'17
DOD: DHP, DARPA, CBD, Army, Navy	DOD: DHP, DARPA, CBD, Army	contracts	1.070 B (100M + health)
DHHS: NIH, FDA, CDC, ACL	DHHS:NIH, FDA, CDC, ACL	both	982.5 M, 1.5M, 11M, 3M
DOE	DOE	both	206.1 M
NASA	NASA	contracts	180.1 M
NSF	NSF	grants	176 M (34M+ health)
USDA		grants	20.3 M
DHS		contracts	17.7 M
DC: NOAA, NIST		contracts	8.4 M
DOT		contracts	7.9 M
ED		contracts	7.5 M
EPA		contracts	4.2 M

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How serious are you and the agencies about commercialization?

- Commercialization Potential is #1 objective mandated by Congress
- Focus on developing a product or service as a solution to an identified, not perceived, problem that the market and customers want.
- Therefore, the commercial potential or viability of the technology needs to be described clearly.

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How serious are you and the agencies about commercialization?

- Agencies/ Departments required to report outcomes
- All awardees have to meet new commercialization benchmarks
- Most Agencies have Technical Assistance Programs (e.g. NIH's Niche Assessment, Commercialization Accelerator, I-Corps programs) and expanding
- Greater emphasis in review + greater expectations at Institute level
- Commercialization History Report if prior Phase II award

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How NIH Funds Biomedical Research

Understand the NIH mission:

*"Seek fundamental knowledge about the nature of behavior of living systems and the application of that knowledge to enhance **HEALTH**, lengthen life, and reduce illness and disability."*

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How NIH Funds Biomedical Research

- Investigator initiated model
- 95% Funding Opportunity Announcements (FOAs)
- 5% Requests for Proposals (RFPs) = contracts

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NIH By the Numbers

- 239 types of funding programs
- Over 2,500 new institutions funded in FY'17 = $17.2 bn
- 55,000 competing (NEW) Research Project Grants (RPG) applications in FY'17:
  - 30,106 RO1s
  - 6,000 SBIR (R41, R42) and STTR (R43, R44)

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Overall NIH Success Rates

Fact check:

- ✓50% of applications are not discussed
- ✓19% rate for RPGs (mostly R01) –this is down from 30% rate 10 years ago
- ✓33% of applications are new
- ✓Pay lines vary by institute and often are not published

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Success Rates

Nr	Phase	Budget ($K)	# Awards (FY 17)	Success rate (FY 17)
1	SBIR I	150 (225 max)	549	16 %
2	SBIR II	1,000 (1,500 max)	194	37 %
3	SBIR II B	3,000 max	21	40 %
4	STTR I	150 (225 max)	169	16 %
5	STTR II	1,000 (1,500 max)	34	39 %
6	Fast-Track (I + II)	1,150 (1,725 max)	101 SB : 15 ST	19 % SB : 17 % ST

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Small Business Innovation Research (SBIR)

- For US small businesses to engage in Federal R&D with potential for commercialization
- Stimulate technological innovation
- Increased private sector commercialization
- Use small businesses to meet Federal R&D needs
- Foster and encourage participation of minorities and disadvantaged persons in technological innovation

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Small Business Technology Transfer (STTR)

- To facilitate cooperative research between US small businesses and US non-profit research institutions, with potential for commercialization
- Stimulate technological innovation and technology transfer

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Eligibility Criteria

- US, for-profit organized, small businesses
- Universities cannot apply
- Foreign entities cannot apply
- SBA size rule: less than 500 employees
- Majority owned by **individuals**, not entities
- Venture-backed as long as no single VC owns majority
- Multiple VCs in total can exceed 50%

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STTR Eligibility

- Requires small business to partner with US research institution, other non-profit research organization or Federal R&D Center
- Applicant and recipient is the small business
- Formal Cooperative Agreement on effort
  - Minimum 40% small business
  - Minimum 30% US research institution
- Intellectual Property Agreement
  - Allocation of IP rights and rights to carry out follow-on R&D and commercialization

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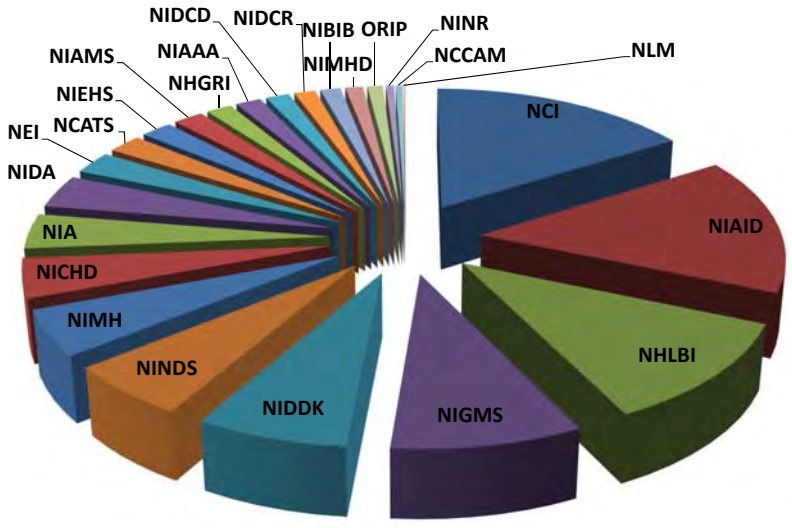
NIH SBIR/STTR Budget Allocations FY2017

3.2% SBIR $861M
0.45% STTR $121M

Total FY17 $982 M



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Main Goal

Develop and bring a product or service to market-readiness a.k.a. commercialization

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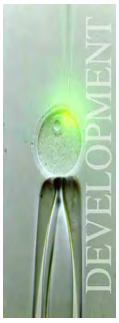
Budgets

PHASE I Feasibility Study

- $150K SBIR & STTR Total Costs **($225 hard cap)**
- 6 months SBIR; 1 year STTR



PHASE II Full Research/R&D

- $1M SBIR & STTR; 2 years **($1.5M hard cap)**

PHASE IIB Competing Renewal/R&D

- Varies $1M/year; 3 years = **$3M max**
- Clinical R&D; Complex Instrumentation, Pre-IND
- Seek 3rd party partnerships and investors early!

PHASE III Commercialization Stage

- **No SBIR or STTR $$:** NIH, generally, not the "customer"
- Plan exit strategy early!

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Budgets and Fees

- Budget requested must be justified against the estimated needs of the proposed project.
- Charge up to 90 days pre-award research to grant.
- Do not exceed the salary cap **$185K total**.
- A **for-profit fee** up to **7%** can be used for expenses not allowed on your grant.
  - Patent costs
  - Market research
  - Expenses outside the U.S.

Facilities and Administrative Costs

- F & A costs are part of direct cost category
- Phase I awards: up to **40%** 'overhead'
- NIH will not negotiate a higher F & A rate for Phase I
- Phase II applicants can negotiate an F &A rate that is higher than 40% with the NIH Division of Financial Advisory Services.

Important Facts to Remember

- Eligibility is determined at time of award
- PD/PI is not required to have a Ph.D./M.D.
- PD/PI is required to have expertise to oversee project scientifically and technically
- Applications may be submitted to different agencies for similar work
- Awards may not be accepted from different agencies for duplicative projects

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Important Facts to Remember

- Awardee has 6 submission cycles 'time window' to submit a Phase II application after Phase I budget closed.
- If outside that time window, must contact program contact for potential waiver for a Phase II application.
- Applicants must submit a re-submission within 37 months of submitting a new (first time) application.
- If a re-submission is not successful, company can submit a new application for next appropriate deadline.

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Data Sharing Policy

- Data from NIH-funded studies should be considered for sharing, BUT proprietary data and privacy safeguarded
- SBIR/STTR data must be protected by NIH for **at least 4 years** from disclosure and non-governmental use
- NIH recognizes constraints in sharing due to institutional policies and other agreements like between private sector collaborators

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Data Sharing Policy

- After 4 years, disclosure can be delayed by up to 60 days
- Methods for sharing data consider sensitivity, complexity, size, volume requested:
  - Archiving
  - Publication
- Data sharing plan now required but does not impact reviewer scoring

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Data Sharing Policy

- STTR program requires SBC and non-profit collaborator to execute agreement that covers allocation of intellectual property rights between parties
- Bayh-Dole Act and Small Business Act provisions apply to SBIR and STTR recipients and render rights to small business to retain IP
- Agreement must be furnished to NIH at time of award

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Data Sharing Plan

- Describe how data will be shared, or explain why it is not possible
- Follows after Research Plan section
- More details and examples at:
  - https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

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Sole Source

- The right to bid for contracts as sole-source
- The right to receive subcontracts for Phase III on sole-source basis
- Benefit to firm and government – months, weeks, not years
- Since government cannot disclose data, it cannot make an award to another firm for work that it cannot describe, thus it can only deal with the SBIR/STTR firm that owns data.

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In every SBIR/STTR FOA:

The competition for SBIR Phase I and Phase II awards satisfies the competition requirement of the Armed Services Procurement Act, the Federal Property and Administrative Services Act, and the Competition in Contracting Act. Therefore, an agency that wishes to fund an SBIR Phase III project is not required to conduct another competition in order to satisfy those statutory provisions. As a result, in conducting actions relative to a Phase III SBIR award, it is sufficient to state for purposes of a Justification and Approval pursuant to FAR 6.302-5 that the project is a SBIR Phase III award that is derived from, extends, or logically concludes efforts performed under prior SBIR funding agreements and is authorized under 10 U.S.C. 2304(b)(2) or 41 U.S.C. 253(b)(2).

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NIH Mindset

- Institutes are becoming increasingly more strategic with managing their portfolios
- Stakeholders interested in ROI, impact
- Increased focus on measuring outcomes = tracking
- NIH changes to making faster awards are coming!
- Expect more reporting on your commercialization efforts
- Applicants need to understand their market before applying for Phase I

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Define Your Objectives
You want NIH to…

- Purchase product
- Award research funds
- Award development funds
- Support clinical research
- Collaborate with your team
- Test/validate product toward FDA approval

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Understand the Technology Portfolio

- Reflects broad NIH research mission = investigator driven ideas and product solutions
- Define your PRODUCT

example:

neuromodulator technology

drug agent ..... pharmaceutical industry

brain implant ..... medical device

behavioral modification ..... health IT

diagnostic assays ..... research tools

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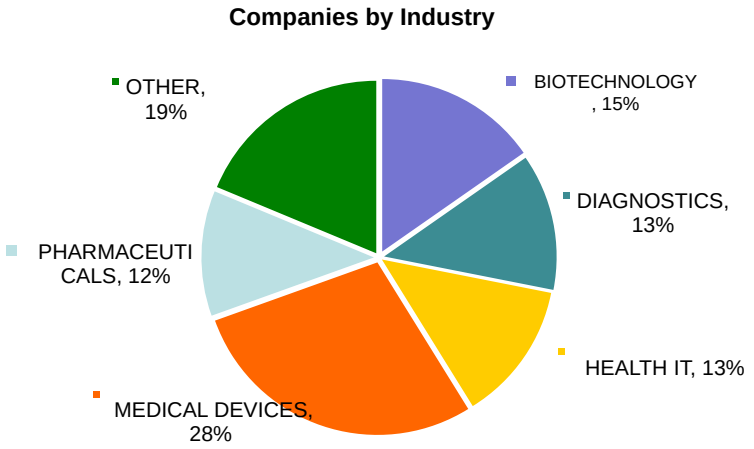
NIH SBIR/STTR Portfolio



OTHER = Research Tools, Educational, Behavioral Modification Tools

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Keys to Success

Give Yourself Time!

Register Early!

Assemble your project team early!

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Required Registrations - take weeks!

- DUNS –required to do business with Government
- SAM – needed for all others, annual renewal
- SBA – one-time company registration
- Grants.gov
- eRA Commons – NIH specific

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SBIR vs STTR

	SBIR	STTR
Partnering requirement	Allows	Requires non-profit partner
Work requirement	Small business work: 67% phase I 50% phase II	Minimum work limits: 40% small business 30% non-profit partner
Principal Investigator (PD/PI)	Primary employment >50% must be with the applicant small business	May be employed by either small business or non-profit partner; Minimum 10% research effort

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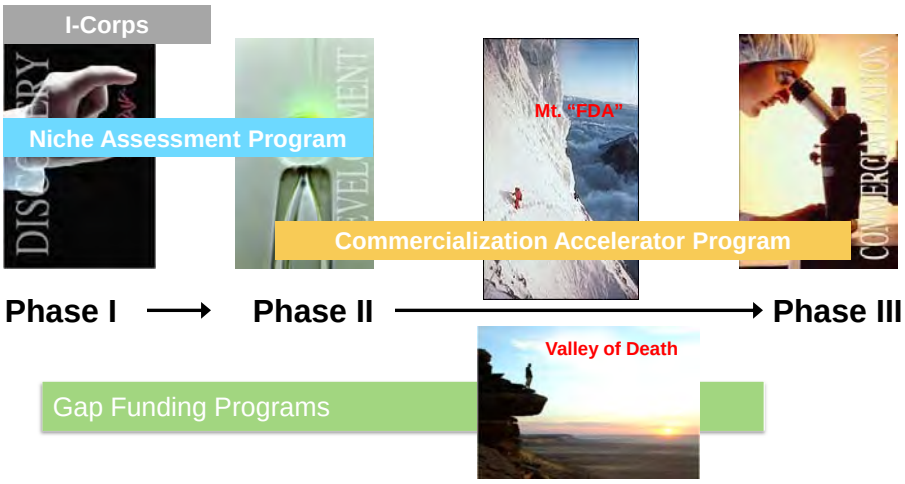
Know your options and plan ahead



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Funding Opportunity Announcements

Annual SBIR/STTR Omnibus Grant Solicitation (NIH, FDA, CDC, ACF)
Standard Due Dates: April 5, Sept 5, Jan 5
~70% of all proposals

No Clinical Trials Allowed:
SBIR: PA-18-574 non-CT
STTR: PA-18-575 non-CT

Clinical Trials Required: NEW
SBIR: PA-18-573 CT
STTR: PA-18-576 CT

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Funding Opportunity Announcements

SBIR Contract Solicitation (NIH, CDC)
PHS 2018 -1
Released: July *October 2018 due date*
For SBIR Phase I, Fast-Track, Direct Phase II contracts

Targeted FOA – varied due dates, review criteria, duration
~30 to 60 released annually

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Gap Funding Programs

Phase I & II Fast Track (Omnibus FOA)

SBIR/STTR Phase I + II one-time simultaneous submission!
Concurrent review (7-9 months)
Phase I Final Report
Milestones met > > Phase II Award Save 6-9 months

Phase IIB (Omnibus and IC-Specific FOAs)

Takes Phase II – developed promising compounds & devices to next stage of medical device/ drug refinement & development

Supports clinical research tools, complex instrumentation, prototype development, larger animal toxicology or early in-human studies for FDA

Maximum $1 M/ year x 3; No Matching Funds Required but expected by some Institutes!

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Important Update

- 2017 re-authorization extended the SBIR and STTR programs until 2022, but ALL pilot programs have expired:
  - Direct to Phase II SBIR = no more skipping Phase I
  - Commercialization Readiness Pilot Program

BUT

- Switching between SBIR and STTR programs IS still allowed

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BREAK

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Q: Why Does NIH Go Beyond Phase I & II?

A: Small businesses have unique commercialization challenges

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- Lack of resources
- Cash Flow “Valley of Death” - risk-averse investors
- Market Validation = who will buy your product or pay for your service?
- Defining Your Customer – Is your technology a “needed” solution to a defined problem?
- Penetrating well-established/ crowded markets = Who is your competition versus strategic partner?
- Barriers to entry - disruptive technologies = adoption risk
- Protecting Intellectual Property = your only “worth” initially

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Technical Assistance Programs

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I-Corps Pilot Program

- Launched in 2014
- For phase I SBIR companies only
- Objective – active customer discovery
  - "get out of the lab" Lean Launch Pad curriculum concept
  - Talk to customers, early adopters
  - Funds for travel available ($25K or more)
- Modeled after NSF - uses program before company formation and for Phase I application
- Other agencies adopting – different structure

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Does I-Corps help everyone?

Case study:

- Type of company: pharmaceutical
  - Typical timeframe to market: ~10+ years
  - When do Pharma companies and investors show interest? : all pre-clinical work completed
  - Feedback through I-Corp exercise: Pharma and investors alike said " come back to us when you are ready to enter clinical trials and you have strong safety and efficacy results"
- Lesson: Not every type of company receives actionable feedback.

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Niche Assessment Program – est. 2004

Phase I SBIR/STTR awardees

Current or soon to be awarded Phase I (Notice of Award)

In-kind service, no $

Technology Niche Analysis ™

Report delivered by contracted vendor:

Identify other uses of technology

Competitive advantages

Market size and potential

Barriers to entry & strategy

Feedback from potential end-users

SBCs use report for Commercialization Plan in Phase II application

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Niche Approach

- Between 150 – 200 slots fill on first come – first served basis
- 1-2 page online application submitted to vendor; NIH verifies eligibility
- Vendor's markets experts interview company, then conduct research and deliver report
- Offered annually in 2 Groups to accommodate newly issued Phase I awards
- Companies may repeat with different active award

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Commercialization Accelerator Program (CAP) - est. 2004

Phase II/B SBIR/STTR awardees

Active or 5 years since completion of project

In-kind service, no $

Personalized Business Mentoring

Service delivered by contracted vendor:

Business & strategic planning

Investor & partnership pitch

Technology Value Proposition

FDA regulatory requirements

IP & Licensing Issues

Exit strategy planning

Go to market, scale up strategies

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CAP approach

- Network Model:
  - It takes a village! – industry domain experts matched up
  - Single principle advisor (coach) assigned for 9 months
  - Your SBIR/STTR "project" will be put into marketplace context
  - Its commercial value is directly related to innovations over current practice, current players and current expectations
  - Comprehensive look at entire company not just the project
  - Commitment from CEO, business decision makers, inventor(s)
  - A long and winding road!

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70 to 80 Companies Selected

10 – month Customized Business Training
Not Curriculum-Based
Not Business Development

Focused Deliverables
Clarified Business Model
18-Month Strategic Business Plan

Commercialization Training Track (CTT)
Broader business training needs

Accelerated Commercialization Track (ACT)
Near-term targeted outcomes

Regulatory Training Track (RTT)
Near-term targeted outcomes

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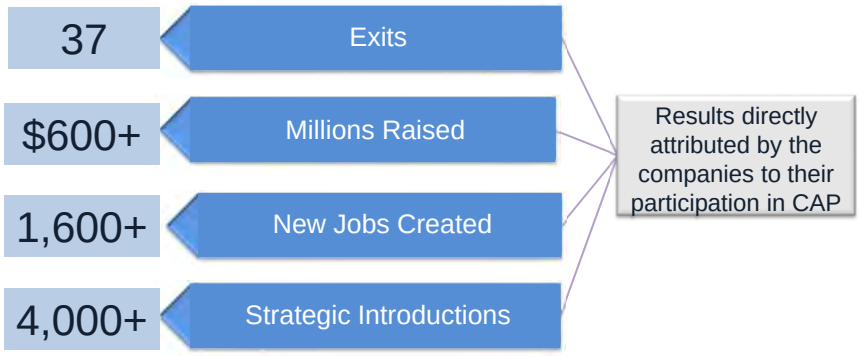
CAP outcomes since 2004



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SUMMARY: Know your options and plan ahead

NIH Award Type	Follow on Funding and/or Technical Assistance Option
Phase I SBIR	Phase II SBIR/STTR; Niche Assessment; I-Corps
Phase I STTR	Phase II STTR/SBIR; Niche Assessment
Fast-Track SBIR	Phase II B SBIR; Niche, Commercialization Accelerator
Fast-Track STTR	Phase II B; Niche, Commercialization Accelerator
Phase II SBIR	Phase II B; NCI Bridge; Commercialization Accelerator
Phase II STTR	Phase II B; Commercialization Accelerator

- Align funding with in-kind technical assistance:
- Agencies use gap funding and assistance programs to leverage initial investment to meet commercialization goals
- Economies of scale benefit for you!

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NIH SBIR/STTR Case Studies and Success Stories

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Lift Labs – Anupam Pathak, CEO/Founder

Lift Labs develops medical devices that help improve quality of life for people suffering from neurological disorders like Parkinson's Disease and Essential Tremor.

- Received over $800K in R&D grants, 1st Phase I in 2010
- 2011 CAP, 2 engineers with no business experience – we suggested use of social media, developed business plan
- *"we learned how to design a viable business around our idea and how to execute a strategy to deploy the technology to general public"-- Pathak*
- Product *Liftware* sold on line initially in 2013
- Acquired by Google X Inc. in September 2014
- 2015 Tibbett's Award winner from SBA

Lesson: Coachability and Execution

LIFT labs

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Actuated Medical, Inc. (AMI)

ACTUATED MEDICAL
Innovative motion + Positive outcomes

- Maureen Mulvihill, CEO/Founder

AMI develops minimally invasive medical devices

- Multiple NIH, NSF SBIR awards directly led to R&D milestones and commercialization of several products, TubeClear and GentleSharp; yielded 10 patents and several jobs
- Participated 3 times in CAP, also Niche:
- *"SBIR helps reduce some of the financial and technical risk for companies to develop products… CAP advisers moved us toward a greater understanding of partnership engagement, and specifically helped us review the terms of distribution deal during negotiations…" - - Mulvihill*
- 2014, Tibbett's Award winner from SBA
- 2014, NIH showcased at AdvaMed and BIO Innovation Zone
- selling directly to MRI lab at NIH –leveraged sole source law

Lesson: Good Communication with NIH, tapping into all resources

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Biopsy Sciences – John Fisher, MD, CEO/Co-Founder

Medical device company revolutionizing lung breast biopsy through minimally-invasive and time-saving procedures

- Est. 2000 by 3 interventional radiologists, now 9 FT employees
- 2002 SBIR for biodegradable soft tissue biomarker for breast biopsies
- 2003 Phase I and 2005 Phase II to research biodegradable sealants for biopsy tracks in soft tissues
- 2007, BioSEAL sold to Angiotech Biopharmaceuticals
- 2014, HydroMARK sold to Devicor Medical Products, Inc., $7M revenues 2013 worldwide
- *"We used NIH SBIR funding to hire employees, and help us patent and commercialize products…, without it we'd likely never have survived." - - Fisher*

Lesson: Focus, defined business model, exit vision

Biopsy Sciences

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SenesTech

SenesTech – Loretta Mayer, CEO/Founder

SenesTech is a platform biotechnology company specializing in reproductive physiology for humane animal population management. Primary objective is to develop products that will sterilize animals in a non-surgical, non-toxic and environmentally neutral manner.

- Received over $9M in R&D grants from NIH, EPA
- CAP 2012 – developed strategy for competitive positioning against well-established market leaders with disruptive solution, strategic partnering alignment
- 2014 NIH-BIO Innovation Zone participants
- 2015 Tibbett's Award winner from SBA
- 2016 IPO (NASDAQ: SNES)

Lesson: Relationship building, focus on growth, good management practices

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What do they have in common?

- Developed relationships with NIH staff
- Regular communication to learn what's new and then leveraging those resources
- Good writing skills
- Persistence

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Due Diligence

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Get Feedback, Build Relationships

- Recognize that:
  - NIH program staff are accessible year round
  - Most FOAs suggest to contact the agency before submitting
  - For some targeted announcements Letters of Intent are expected
- Proactive communication conveys you are professional, diligent, committed!
- Preparation instills confidence you respect their time and the process

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Best practices and tips

- There is strategy to winning an award beyond great science:
  - preparation, communication, follow-through
- What do successful companies/ people have in common?
  - sense of urgency >> good solution >> execution
- How is success defined at NIH SBIR/STTR?
  - advancing development of technology toward intended market and customers
  - demonstrating commitment to growth and commercialization
  - public health mission

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Best practices and tips

- Communicate with NIH Program Officers BEFORE applying – gauge interest and get their support
- Allow 4-6 weeks for required registrations
- SUBMIT EARLY!
- Allow time to resolve Errors = stop application
- Allow time to resolve Warnings = can continue

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Do Your Homework

- Understand Research Areas of Interest:
  - Review the Program Description and Topics Guide
  - Research previously funded projects in the RePORTER database
  - Read the Funding Opportunity in DETAIL - it takes precedence over the instructions in the SF424 Application Guide

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Concept Write UP: Why Do It?

- Proven, efficient tool to discuss your project with NIH staff.
- Forces you to focus on project objectives and Specific Aims
- Sets the roadmap for the entire proposal
- Elicits constructive feedback!
- Builds positive rapport with program staff
- Adopt the practice before every submission

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Resources

NIH SBIR/STTR Webpage

- http://sbir.nih.gov

NIH Guide for Grants and Contracts (weekly notification)

- http://grants.nih.gov/grants/guide/listserv.htm

NIH SBIR/STTR Notification

- Email LISTSERV@list.nih.gov with 'subscribe SBIR-STTR your name' in the message body:

NIH RePORTER (public database of all funded projects)

- https://projectreporter.nih.gov/reporter.cfm

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Review Process at a Glance: Criteria and Expectations

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Electronic Submission

- ASSIST – new web-based application platform
  - For grants only
  - Eliminates downloadable PDF forms
  - New Forms-E
  - Circumvents Grants.gov step !
- eCPS – electronic contract proposal submission
  - These go through a different review at Institutes but adhere to same program rules plus FAR

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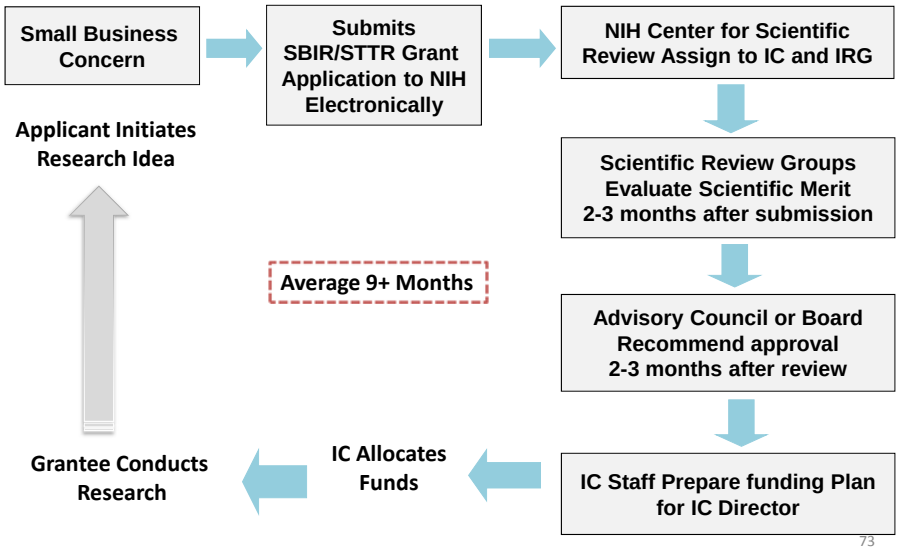
Two-Tiered Peer Review at NIH



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Review Panels

- All external to NIH: academic researchers, business experts (many SBIR/STTR awardees themselves, technical consultants
- Other agencies:
  - mix of external/ internal (NSF) or all internal (DOD and other procurement agencies)
  - Different submission procedures
  - Different application sections

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NIH Review Criteria – Scored Sections

Overall Impact Score - Impact is the reviewer's final judgment of the overall merit of an application and is the only score that determines funding.

Scored Review Criteria **(score 1-9)**

- ❑ Significance (Real Problem/Commercial Potential)
- ❑ Investigators (PI and team)
- ❑ Innovation (New or Improved?)
- ❑ Approach (Research Design, Feasible)
- ❑ Environment (Facilities/Resources)

Additional Review Criteria **(not scored individually)**

- ❑ Protection of Human Subjects
- ❑ Inclusion of Women, Minorities & Children
- ❑ Vertebrate Animals
- ❑ Biohazards

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What About the Commercialization Plan?

- It is not scored, but reviewed as part of Significance
- Phase II/B only
- It is 12 pages long

- Provides details on innovation, competition, market size, company efforts, etc. in a structured format that does not fit within the Research Section

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Research Strategy vs. Commercialization Plan

- Should align in what key points and strategies they express.
- Even though not scored, the CP improves overall competitiveness of application
- A good CP supports your Research Strategy
- CP even more relevant for Phase II follow on programs like Phase IIB or NCI Bridge.

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Keys to Success

Have a good product, not idea, to test

Have a commercialization strategy before applying for Phase I

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Checklist of Application Sections

section	Phase I (pages)	Phase II (pages)
Introduction (only re-submissions)	1	1
Project Narrative	3 sentences max	3 sentences max
Project Summary (Abstract)	30 lines	30 lines
Specific Aims	1	1
Research Strategy	6	12
Biosketches	5	5
References Cited	-	-
Equipment	-	-
Facilities	-	-
Resource Sharing Plan	-	-
Authentication	-	-
Commercialization Plan	NA	12
Budget Justification	-	-
Letters of Support	-	-
SBA Registration	Download PDF	Download PDF

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Checklist of Application Sections

section	Phase I (pages)	Phase II (pages)
Vertebrate Animals	? 1-2	? 1-2
Human Subjects protocol	?	?
Subaward Budget/ Justification	-	-
Consortium Agreement (STTR)	-	-
Other FOA specific requirements	-	-

80

Optional, but recommended

- Assignment Request Form:
  - Request which Institutes
  - Request study sections to review your application
  - Indicate type of expertise needed for review
- Cover Letter:
  - reflects your conversation with Institutes, what you are submitting, your requests and any special, relevant circumstances

81

Lunch Break
45 min

82

Specific Aims

In-class Exercise

83

Specific Aims

- Big picture of your project but very SPECIFIC
- 1 Page : split it in two halves
  - Part I – project executive summary
  - Part II – hypothesis and specific aims
- If you don't know the scope of your project and what you want to accomplish, how can you write about it?
- NIH expects you to do the scope of work that it funds!

84

Reminder

- Phase I : 6 months to 1 year
  $150 K up to $225K
  Establish technical/ scientific merit and demonstrate feasibility of R&D effort
- Phase II : 2 years
  $1 M up to $1.5 M
  Continue R&D efforts initiated in Ph I
- Fast-Track : 2.5 years
  $1.15 M up to $1.75 M

85

I: Answer these questions

What are you developing?

Why, what is the problem? Unmet need, limitations?

Cite evidence: Have others tried & failed? What does the literature say?

Why is your product better = what is innovative? Compare current solutions against yours. Are there any similar products (FDA-approved?)

Who is the product for and how/where will it be used?

86

I: Answer these questions

What is the objective for your project?

Have you conducted preliminary research and what did you find?

How do these findings support your main scientific premise behind this technology?

What will be the overall impact? Likelihood to sustain impact on the discipline, practice, science?

87

I: Answer these questions

If Phase I, how will successful completion of proposed work enable Phase II activities?

If Phase II, what did you demonstrate in Phase I, and what will be the commercialization activities?

Phase II aims cannot be mere extensions of Phase I, they have to logically advance the development of the technology toward commercialization.

88

II: Specific Aims Structure

Phase Is – 1 to 3 Aims

Phase IIs – 2 to 4 Aims

Helpful to frame Aims as questions:
What specific activity will achieve the goals?
How will you prove the hypothesis?

89

II: Specific Aims Structure

Each Specific Aim should include a Milestone.

Milestone = a measurable, quantifiable output from completed task(s), that means a successful outcome is achieved. A.k.a. acceptance criteria.

Consider how long each task will take.

90

#1 Example of Objective

In Phase I, COMPANY proposes to develop a state-of-the-art actuator/ controller system for a hand held device, and to demonstrate feasibility in a proof-of-concept prototype. We will evaluate three possible actuator technologies X, Y, Z, and characterize the one found to be the most suitable for the application.

To demonstrate proof of feasibility, the resulting miniature actuator, sensor and controller will be incorporated in a hand-held proof-of-concept device.

Phase II work will focus on refining the device technology with patient input to create a commercial product. At the end of Phase II, we will be ready to launch this highly-portable device for X patients.

91

#2 Example of Objective

In this Phase I we will establish the technical merit and feasibility of creating and using the online training system, “the X”.

The proposed SBIR Phase II will develop and rigorously evaluate the effectiveness of an online training and support system, “the X”.

To test the effectiveness of the “X”, we will conduct a pre-test/post-test randomized controlled trial in two aims: …

If this model proves to be effective, the online skills-based training developed under this grant will provide an accessible, low-cost, training and implementation support service.

92

#1 Example of Aims

Phase I hypotheses: product X prototype demonstrates superior safety (50% improvement in retained lung tidal volume) and superior efficacy (cleaner ET and same amount of time) compared to standard suction catheter in 2.5 mm ETs.

Hypothesis testing will be in two aims:

Aim 1: Finalize closed system design and construct alpha prototypes for optimization testing (months 1 – 4). Prototype will meet specification within acceptable range of XX units.

Aim 2: Optimize product X parameters for mucus removal with minimal impact on tidal volume compared to baseline impact of current suction methods (months 5 – 6).

Aim 3: Final testing of product X compared to standard care (months 6)

93

#2 Example of Aims

The proposed research has 2 specific aims:

Aim 1: to prepare and characterize neutralizing Ab for preclinical product candidate evaluation. The quantitative milestone is to establish the minimum saturating dose of Ab that produces effective anticoagulation for at least 24 hours in baboons.

Aim 2: to determine the efficacy of Ab compared with X in a baboon venous thrombosis model. The quantitative milestone is to document a significant antithrombotic effect of Ab, at a saturating dose, comparable to that achieved by a clinically relevant dose of X.

94

Write Your Own Aims

Project goal:

Aim 1:

Aim 2:

95

Aim :

Aim :

Impact statement:

96

BREAK

97

NIH Application Outline
Scored Sections

98

Significance

- Understand and quantify THE PAIN?
- What has been done and who is doing related research = competition?
- You have done research on this problem
- Scientific Premise: strengths & weaknesses of published research in support of your application
- Objective: your proposed solution
- Impact on clinical practice, research field
  - Benefits to whom? How are you better, different?
  - How will you demonstrate feasibility?
- Anticipated outcomes and they will advance commercialization of this innovation

99

Common Critique

- Proposed technology claims it will be superior to other, but no direct comparison is proposed
- Questions about the premise itself – significant and sustained impact on field not clearly articulated
- Market may be small or crowded, or size or segment unclear

100

Innovation

- Demonstrate knowledge of state of the art
- Describe novel theoretical concepts, approaches, instrumentation
- Describe advantages over existing solutions
  - Its OK to include diagrams, within reason
- Explain refinements or improvements and their application

101

Common Critique

- The proposed approach/ technology is not novel, demonstrates applicant doesn't know competition
- Advantages over other competitors / predicates are not clear
- Lack of details and technical discussion of product (engineering drawings, schematic diagrams) not allowing full evaluation
- Unsubstantiated claims, vague statements

102

Approach

- Looking for clearly written, neat, logically flowing study design
- Details of methods used, justifications and rationales for what, why and how hypothesis will be tested to achieve proposed Aims
- Rigorous application of scientific design
- Relevant, supporting preliminary findings
- Discuss potential problems and alternatives

103

Approach

- Explain benchmarks for success
- How will you interpret the data
- Address management of any high-risk aspects of proposed work
- Explain any relevant biological variables:
  - gender choice in animal or human studies
  - hazardous materials, select agents
- Project timeline – table of tasks over the project period

104

Common Critique

- Comparative studies to prove superiority are not proposed
- Questions regarding study design, such as choice of study model, rigor of testing, statistical analysis
- Lack of consideration for potential complications or mitigation plan
- Proposed Aims too ambitious or poorly designed (interdependency, unclear end points)

105

Common Critique

- Lack of description of the product itself and how it would be deployed
- Lack of detailed description of procedure
- Not clear where work will be performed
- Formatting issues: perceived sloppiness due to typos, indents, varied text formats, out of place text (remnants from other drafts)
- Missing project timeline

106

Common Critique

- Preliminary data shown do not support proposed Aims
- Preliminary work mentioned, but no data shown

107

NIH Application Outline Scored Sections

Investigators =

Biographical Sketches

Overall Team: Advisors, Consultants

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Investigator(s)

- Reviewers look for a team that has
  - needed technical and relevant industry expertise
  - PD/PI should be well-published in the area meet program criteria
  - Past track record in funding, managing and completing other projects
  - Worked together
- Biosketch is not a resume, tailor it according to the instructions and for the specific project

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Common Critique

- Biosketch on old template or varied fonts due to cut-paste from old files, unrelated text
- PD/PI not well published
- Not clear who is the lead for project
- Commitment of time and effort questions
- Vaguely defined roles of team members
- Lacking clinical expertise (if human subjects)
- No product development experience (find KOL's, advisors)

110

NIH Application Outline
Scored Sections

Environment
=

Facilities & Other Resources

Equipment

Letters of Support

111

Environment

- Looking for appropriate facilities where studies will be conducted
- Company should secure/ have access to equipment needed to successfully carry out project
- Include facilities of subcontractors
- Letters of support – lease agreements, fee for service quotes that are also justified within budget

112

Common Critique

- It is not clear where X work will be conducted
- It seems majority of work will be outsourced to university or CRO
- Support letter of commitment from X not included, not confident resources will be in place at time of award

113

BREAK

QUESTIONS ?

114

Commercialization Plan and Strategies

115

Your Company's Objective Should Be:

- to achieve market readiness,
- customer relevance,
- commercial relationships and product/service revenue in the marketplace.

- not linear: you must plan for deviations from any "business plan" just as you plan for contingencies in your "research plan"

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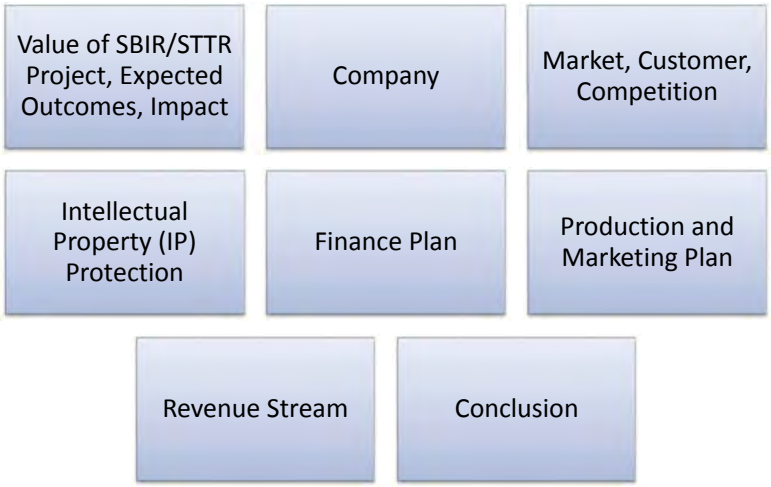
Recall #1 Eligibility criterion? Organized as for-profit U.S. business

- 3 Points:
  1) When you accept funding, you have an obligation to produce value to the taxpayer
  2) You receive a for-profit fee (up to 7%) as incentive for conducting business
  3) New Commercialization Benchmarks must be met, if have other Phase II awards, must submit Commercialization History with application.

117

Commercialization Plan: you have 12 pages – Use Them!!



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1. Value of the SBIR/STTR Project, Expected Outcomes, Impact.

Describe, in layperson's terms, the proposed project and its key technology objectives. State the product, process, or service to be developed in Phase III. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR/STTR project integrates with the overall business plan of the company.

- Flows from your Significance section
- Make the case why your product is the better choice = Show me the DATA!
- Articulate the impact of expected outcomes on intended customer
- How do you define a successful project outcome?

  Formula: If X result, then Y next step possible.

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2. Company

Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you will grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

- Talk about your most valuable assets: people, facilities, equipment, partnerships and collaborations.
- Address any future plans to grow and secure resources
- Describe any commercialization activities
- Generate a ‘project organizational chart’

120

Guiding questions to ask yourself

- What is our business model? = how will we make money?
  - = who do we want to be when we "grow up"?
    do we build it or outsource manufacturing?
    do we provide tech support to customers?
  - = what is our exit?
- This is my baby, no one else is as passionate as I am. BUT are you the right person for the job? Giving up control is very hard for founders as company grows.
- Are we trying to do too much? Focus, Focus, Focus

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3. Market, Customer, Competition

Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation.
Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product. Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. (It is very important that you understand and know the competition.)

- Size of market opportunity – how many people sick, how much potential market cap?
- What percent of the market you will capture?
- Barriers to entry = the adoption problem
- What is the regulatory and reimbursement climate like?

122

Guiding questions to ask yourself

- Market and customer characterization
  - The market “problem”
  - Is your technology a “solution”?
    - If I build it, will they come?
  - Reality check: is anyone out there already doing this?
  - How good is the competition?
    - *How do you compare against it*
- Have you spoken to customer?
  - How much will they pay?
  - How will they use the product?
  - What is the inertia?
- Regulatory landscape
  - How do we meet FDA’s expectations and requirements?

123

Claims and Indications of Use

- What does the customer/ FDA care about?
  - Safety and Efficacy
- Define Product features, intended effect
- Establish a Roadmap: deconstruct the problem and work backwards from defined product or service
- What are the discrete tasks you have to accomplish to reach specific milestones?

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Sample Competitive Matrix

Your Product Features		Competitor 1 (Product/Make r)	Competitor 2	Competitor 3	Competitor 4
A	✓	✓	✓		
B	✓	X	✓		
C	X	✓	X		
D	✓	X	X		
E	✓	X	X		

- TIP: Reverse engineer from intended use of product to what you claim are the benefits of your product
- Do market research to understand your competition – Reviewers look for this!

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4. Intellectual Property (IP) Protection

Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to yours.

- Clearly describe what IP you own versus other parties – this is often reviewer critique
- Just saying technology is *novel* is not enough!
- Differentiate – compare competition, current products or approaches, how is your product better? Innovation heavily scrutinized by reviewers.
- If have pending or issued patents, include a table. Mark any proprietary unpublished text! When in doubt, don't include details.
- Remember: Patents are not required, but plans to protect IP are expected.

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5. Finance Plan

Describe the necessary financing you will require to commercialize the product, process, or service, and when it will be required. Describe your plans to raise the requisite financing to launch your innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways: Letter of commitment of funding. Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist. Letters of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation. Specific steps you are going to take to secure Phase III funding.

- What financial resources do you have now?
- How much money do you need for specific R&D activities under this proposal and related studies, how will you plan to raise that money and when?
- Account for hiring people, leasing space, paying for rent and equipment and paying regulatory consultants, lawyers, other help.

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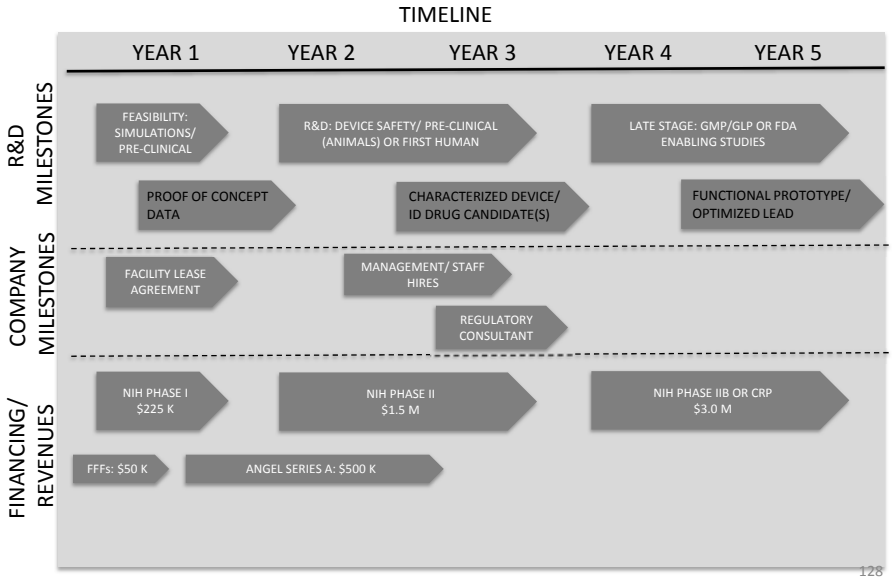
Product Development Roadmap



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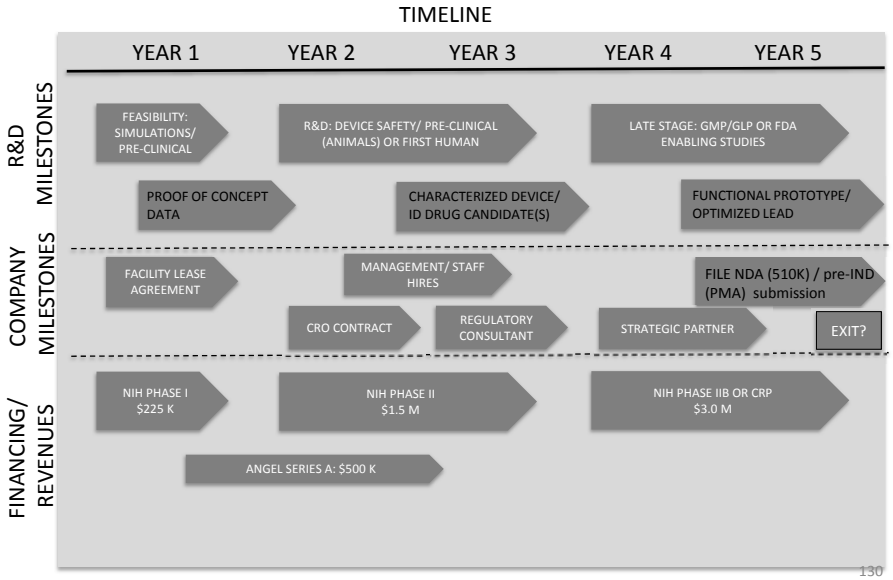
6. Production and Marketing Plan

Describe how the production of your product/process/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/process/service. For example, explain plans for licensing, Internet sales, etc.

- Don't forget to describe the regulatory path
- What certifications and other compliance measures will you have to meet?
- Where will you make the product or parts of it?
- Your future plans reflect your ultimate EXIT strategy as you define it today.

129

Product Development Roadmap



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7. Revenue Stream

Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.

- Generate a 5-Year Forecast for the company
- Don't forget the Government can often be your first customer!
- If you are not starting sales in that timeframe, project future R&D revenues from anticipated grants/contracts

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Guiding questions to ask yourself

- Business and financial strategy
  - Licensing potential?

    generate revenues

    IP strategy: make sure you have FTO
  - How do you plan for financial sustainability?

    Recurring revenues
  - What are your key income and key expense factors?
  - The color of the money?

    Personal preference vs. company need
  - Who do we hire, when, and what salary?

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Revenue Projections: Example

Source of Revenues	2017	2018	2019	2020	2021
SBIR Ph II animal studies	1M	1M			
SBIR Ph IIB Tox studies	-	-	1M	1M	1M
SBIR Ph I (new technology)			$225K	-	-
SBIR Ph II (new technology)	-	-	-	$1M	800K
Venture Series A (IND/ IDE enabling)	-	-	-	2M	4.5M
Licensing Revenues (Lead Product) or Sale					X (EXIT?)
Lab Services Revenues	-	30K	50K	75K	125K

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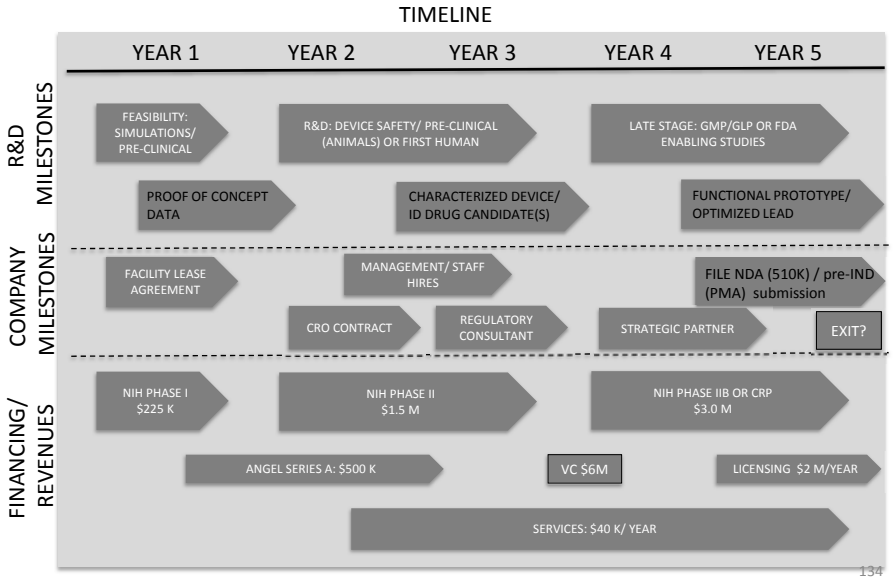
Product Development Roadmap



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Conclusion

- Summary of what successful outcome of Phase II project will lead to/ enable
- Do you have letters of support, interest, commitments, conditional orders? Brag about them!

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Workshop Wrap-Up

Winning an award is more than 25 page of good technical writing.

- Long-term strategic decision
- Compelling business proposition
- Ability to create relationships with customers
- Consistency in sound business practices

Don’t give up on a good idea!!!

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Open Discussion

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THANK YOU

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