SBIR/STTR Workshop

Provided by:
Ripple Technology
(previously Ripple Management)
and
MUSC

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Topics and Technology Roundtable
Know Your Customer
Why does the SBIR program exist?

- Create companies that pay taxes
- NIH: Solve public health problems

NOTES:

- They expect you to find and understand the customer / patient
- They are not the end customer
SBIR - Small Business Innovation Research
2.5% set-aside

STTR - Small Business Technology Transfer
0.3% set-aside
# Phases

<table>
<thead>
<tr>
<th>PHASE I</th>
<th>$150,000</th>
<th>6 TO 12 MOS.</th>
<th>Feasibility</th>
<th>33%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHASE II</td>
<td>$1,000,000</td>
<td>2 TO 3 YEARS</td>
<td>Product Developmen t</td>
<td>50%</td>
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</tbody>
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Phase I required ➔ Phase II ➔ Phase III

Note: some agencies allow Phase II applications by request only

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Fast Track

- Phase I + Phase II ---- ONE Application
- Removes review cycle between PI and PII
- Required Commercialization Plan

- Are you commercially ready?

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# Application Criteria

<table>
<thead>
<tr>
<th>REVIEWERS</th>
<th>CRITERIA</th>
<th>SCORING</th>
<th>EXTRAS</th>
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</thead>
<tbody>
<tr>
<td>NIH</td>
<td>Peer Review</td>
<td>Significance</td>
<td>0 to 90&lt;br&gt;&lt; 28 fundable&lt;br&gt;Review Panel&lt;br&gt;selection = critical!</td>
</tr>
<tr>
<td>SBIR Special Emphasis Panels</td>
<td>Investigators&lt;br&gt;Innovation&lt;br&gt;Approach&lt;br&gt;Environment</td>
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NIH Review Criteria

• **SIGNIFICANCE** - How important is the problem?
• **INVESTIGATORS** - How qualified is the team?
• **INNOVATION** - How important is the PRODUCT?
• **APPROACH** - How well designed is the research?
• **ENVIRONMENT** - How critical are the collaborators and environment?

*Most important

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SIGNIFICANCE
NIH Significance

(One page or less)

• Stats about the population affected
  – How many people are effected?
  – How much does this problem cost the healthcare system?
  – Who is effected?
    • Doctors? Nurses? Hospitals? Patients? Insurers?
• What discoveries are needed (provide current solutions and their limitations)?
  – What are people doing now?
    • Who offers the current solution?
    • Are patient / doctors doing nothing to solve it?
  – How is the current solution problematic or costly?
    – Why is their no current alternative?
NIH Significance

(One page or less)

• What is the trigger point for change?
  – There is often a point at which companies, patients, etc. will change
  – You need to know where that point of change is...
  – For example:
    • At a 10% cost reduction, no change happens
    • However, at a 40% cost reduction, everyone wants it
NIH Significance

(One page or less)

• Have you picked the right target?
  – Sometimes you may have a great solution for one disease, but the need may be higher in another area

• How to find out?
  – Ask a few potential program managers
  – Ask industry experts in more than one area (e.g. colleagues, potential buyers, potential partners)
  – Submit and find out what reviewers say
INNOVATION
NIH Innovation

(One page or less)

• Why is your product innovative (provide as much details as possible such as better, faster, cheaper etc.)?
  – Be honest about your ability to make an impact
  – What hard proof do you have to support your argument?
NIH Innovation

(One page or less)

• Is your intellectual property protected?
  – Are others patenting or publishing on your topic?
  – Google
  – Google Scholar
  – PatentLens.com
NIH Innovation

(One page or less)

• What is your regulatory and reimbursement path?
  – Is something potentially blocking your path?
  – How will you get reimbursed or paid?
NIH Innovation

(One page or less)

• What are the public health implications?
  – How much of an impact will you make on the significance you outlined?
  – Quantify your impact over and above the competition
NIH Innovation

(One page or less)

• Financial Projections (generally in Phase I; in greater detail for Phase II)
• After Phase II what additional steps will necessary to realize profit
  – What is your path to market?
  – Regulatory, reimbursement, etc.?
  – How much will it cost? How far will SBIR funds get you?
SPECIFIC AIMS
NIH Specific Aims

(One page or less)

• Paragraph 1
  – Problem and Significance
    • How many people? How much does it cost the system? Who is effected? (e.g. Doctors? Nurses? Hospitals? Patients? Insurers?)
  – Current solutions, gaps, roadblocks
    • What discoveries are needed (provide current solutions and their limitations)?
    • What is the trigger point for change?
NIH Specific Aims

(One page or less)

• Paragraph 2
  – What is your Product?
  – Why is it an innovative solution to the problem?
  – How does it overcome the current “gold standard”?
  – Competition?
  – Intellectual Property?
  – Is the regulatory and reimbursement path clear?
NIH Specific Aims

(One page or less)

• Bullet Points (Approach or Statement of Work)
  – What can you do with $225K?
  – What do industry experts say you need to prove feasibility?
  – What is the gold standard?
  – What are your product milestones?
  – Timeline / next steps
SPECIFIC AIMS
EXERCISE / REVIEW
Questions?

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Appendix
Everybody loves a good story!
Components of a Good Story

- Customers
  - NEED / PAIN
  - Money $$$
- Defendable market position
  - Strong IP
  - Barriers to entry
  - Unfair competitive advantage
- Reasonable market
  - Government will be investing $1.5M
Competition

What are your potential customers doing right now?
Product Focused

- Product Aims, not Research Aims
- Innovative Product, not Innovative Experiments
- Company Objectives, not Science Objectives
NIH Proposal Format

• **Specific Aims (no more than one page)**
  – Paragraph 1: Problem and Significance; Current solutions, gaps, roadblocks
  – Paragraph 2: Your Product; Why it is an innovative solution to the problem
  – Specific Aims (Bullets for each): Easily assessed by reviewer

• **Significance (Public Health Problem) – 1 page or less**

• **Innovation - 1 page or less**

• **Approach – Follows aims**