Beyond Research: Building a Business

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Rob Vinson
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“Beyond Research: Building a Business”

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NIH Small Business Program Manager, SEED (Small business Education & Entrepreneurial Development)
Office of the Director | Office of Extramural Research | National Institutes of Health
New Support for Awardees

Technical and Business Assistance (TABA)

TABA Needs Assessment

TABA Funding
(requested in grant application)

Education

I-Corps at NIH *Phase I
Concept to Clinic:
Commercializing Innovation
(C3i) Program

Funding and Support

CRP Funding *Phase II/IIB
Regulatory & Business Development Consultants

Partnering and Investment Opportunities

Company Showcase

https://sbir.nih.gov/support-for-awardees
The Technical and Business Assistance (TABA) Program helps small businesses identify and address their most pressing product development needs.

Enables companies to:
• Make better technical decisions
• Solve technical problems that are beyond the scope of the funded R&D
• Minimize technical risks
• Commercialize the product
• Grantees may request TABA Funding as part of their grant or as a supplement (NOT-OD-21-062)

• TABA costs **may not** exceed:
  – $6,500 in additional funding **per year** for a Phase I
  – $50,000 in additional funding **per project period** for a Phase II

• Institutes/Centers can set individual budget and TABA guidelines

• Projects that are awarded TABA Funding **cannot** use centralized TABA Programs (TABA Needs Assessment) during that SBIR/STTR Project Phase
Support subcontractor or consultants for:
- Assistance with product sales,
- Intellectual property protections,
- Market research and/or validation,
- Development of regulatory plans,
- Development of manufacturing plans,
- Access to technical and business literature available through on-line databases.

Funding cannot support:
- Activities done by:
  - Recipient small business
  - Affiliates/investors
  - R&D subcontractor/consultant
- Contributions to the SBIR/STTR fee
- Activities outside the scope of the award
- Contingency costs or costs associated with the award R&D
- Audit or Bookkeeping services
Help small businesses identify and address their most pressing product development needs.

**TABA Needs Assessment Report**

- Validates request for TABA funding
- Helps Company write a strong Phase II Commercialization Plan

- Summary Analysis/Company Summary
- Target Market Attractiveness
- Technology and Market Needs
- Regulatory/Clinical
- Business Model Profitability
- Reimbursement
- Competitive Advantages/Intellectual Property
- Market Access/Sales and Marketing Strategy
- Management Team
- Strategic Partners
- Funding Status
- Recommended Actions/Plan

110 companies participating since launch in November of 2020.

"Information received was critically helpful in our business plan."

"It is like having a professional roadmap."

https://sbir.nih.gov/support-for-awardees/tab-needs-assessment
Eligibility:

SBIR or STTR recipients (grant or contract) with:

- Active NIH Phase I or Phase II OR
- Within two years of the completion of an NIH Phase I

- Projects that received Niche Assessment or TABA Funding in the Phase I are ineligible

- Participation in other Support Programs (e.g., I-Corps at NIH or C3i) does not make a company ineligible
Request Process

- Open all year
- **MUST** submit a request at: [https://sbir.nih.gov/support-for-awardees/tab-a-needs-assessment](https://sbir.nih.gov/support-for-awardees/tab-a-needs-assessment)
- Requests are reviewed monthly
- Notification of status within 60 days of submission
- Report is completed in 2-3 months
I-Corps at NIH

MICHAEL WEINGARTEN
SBIR DEVELOPMENT CENTER
NATIONAL CANCER INSTITUTE
I-CORPS at NIH

- Funding Opportunity Announcement (FOA) **PA-19-029**

- Intensive *Entrepreneurial Immersion* course aimed at providing teams with skills and strategies to reduce commercialization risk

- Curriculum emphasizes *Reaching out to Customers* to test hypotheses about the market(s) for the technology

- Teams are expected to conduct over **100 interviews** in 8 weeks

- Format is focused on *Experiential Learning*

- NCI SBIR designed, launched, and manages the program for NIH

- 24 Institutes at NIH and CDC participate

https://sbir.cancer.gov/icorps
TOP 10 STARTUP MISTAKES

1. Building something nobody wants
   Score: 300 (36% of Tot.)

2. Hiring Poorly
   Score: 153 (18% of Tot.)

3. Lack of Focus
   Score: 112 (13% of Tot.)

4. Fail to execute Sales & Marketing
   Score: 98 (12% of Tot.)

5. Not Having the Right Co-Founders
   Score: 66 (7.9%)

6. Chasing Investors, Not Customers
   Score: 45 (5.4%)

7. Not Making Sure You Have Enough Money
   Score: 28 (3.3%)

8. Spending Too Much Money
   Score: 18 (2.1%)

9. Failing To Ask For Help
   Score: 12 (1.4%)

10. Ignoring Social Media
    Score: 6 (0.7%)
Commercialization Plan – Business Model Canvas
Please rate the following components of the I-Corps course to date in terms of their impact on your team's learning.

<table>
<thead>
<tr>
<th>Component</th>
<th>Before</th>
<th>After</th>
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<tbody>
<tr>
<td>Channels</td>
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<td>Cost Structure</td>
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<td>Customer Relationships</td>
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<td>Customer Segments</td>
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<td>Key Activities</td>
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<td>Key Partners</td>
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<td>Key Resources</td>
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<td>Revenue Streams</td>
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<tr>
<td>Value Propositions</td>
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</tbody>
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13
I-CORPS CASE STUDY - MEDABLE

Ingrid Oakley-Girvan
SVP, Research and Strategy
I-Corps at NIH – 2018

• Validated areas of unmet need as opportunities; 4+ new commercial apps
• New TeleVisit™ mobile app enables clinical trial research to progress in a social distancing setting and is used by leading biopharma sponsors and clinical research organizations worldwide
• Secured $91 million in Series C funding and has raised more than $136 million to date.
**NCI SBIR ASSISTANCE**

<table>
<thead>
<tr>
<th>Before Phase I</th>
<th>SBIR Phase I</th>
<th>SBIR Phase II</th>
<th>SBIR Phase IIB Bridge Award</th>
<th>Commercialization</th>
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<tbody>
<tr>
<td>Application Assistance Program</td>
<td>I-Corps at NIH</td>
<td>NCI Investor Initiatives</td>
<td>NCI Peer Learning and Networking (PLAN) Webinar</td>
<td>NCI Resources for Commercialization Workshops</td>
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<td>CEO Roundtable</td>
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<td>Connecting Awardees to Regulatory Experts (CARE)</td>
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 Crossing the “Valley of Death”

Nonfederal Funds

[https://sbir.cancer.gov/resources](https://sbir.cancer.gov/resources)
# 2020 New Opportunity I: Small Business Transition Grant

## Phase I STTR

### Training
- SBC PI: Postdoc
- Mentoring plan required
  - Technical Mentor
  - Business mentor

### Technical
- PI preps technology to move to SBC
- I-Corps at NIH required

## Transition

### Personnel
- PI moves to SBC

### Technical Update
- R&D Milestones
- Commercialization plan
- IP agreement

## Phase II SBIR

### Training
- Same PI (non-transferrable)
- Mentoring Continues
  - Contact type and frequency in mentoring plan

### Technical
- Most research conducted at SBC site
- Small pivots allowed
  - No major scope changes
The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

______________________________

NHLBI’s Strategic Goals:______________________________

- Understand Human Biology
- Reduce Human Disease
- Develop Workforce & Resources
- Advance Translational Research

Innovation office supports advancing translational research
Funding and Support for NHLBI Innovators

- Supports the NHLBI innovator community to validate and advance discoveries to products that improve patient care and health.

- Develop relationships with strategic partners and build opportunities for NHLBI innovators to further their product development efforts.

- **Academic Innovation**
  - NCAI/REACH
  - CAPCaT
  - Catalyze

- **Small Business Innovation**
  - Application Review
  - Conference Support

- **Innovator Support**
  - Product Development Support Services

- **Diversity Programs**
  - AAP
  - Diversity Supplement

- **Commercialization programs**
  - I-Corps™
  - C3i
  - TABA Needs Assessments

- **Awards to Accelerate Commercialization**
  - SBIR Phase IIB Bridge Award
  - SBIR Phase IIB Small Market Award

- **NHLBI Mentor Network**
  - Mentorship services
NHLBI Innovation Office Support Services

One on One Advisory Services
Contact NHLBI specialists with specific questions:
- SBIR/STTR applications
- Regulatory
- Business development
- Intellectual property

Product Development Support Services
- National Mentor Network – targeted company support
- Showcase Events - offers conference registration fees to industry partnering and investor meetings
- Pitch coaching for Showcase Events

“Small Biz Hangouts” YouTube Playlist
- Series of videos regarding common issues that biomedical innovators face.
- Go to bit.ly/SmallBizHangouts

Website: sbir.nih.gov/nhlbi
**NHLBI Catalyze Program**

### Early Translational Research Supported by Catalyze*

<table>
<thead>
<tr>
<th>Disease Target</th>
<th>Product Definition</th>
<th>Preclinical</th>
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</thead>
<tbody>
<tr>
<td>Concept</td>
<td>Develop Assay</td>
<td>Lead Optimization</td>
</tr>
<tr>
<td>Design</td>
<td>Hit-to-Lead</td>
<td>Animal Safety &amp; Efficacy</td>
</tr>
<tr>
<td>Prototype Development</td>
<td>Mechanism of Action</td>
<td>Preclinical</td>
</tr>
<tr>
<td>Product Generation</td>
<td>High-throughput Screening</td>
<td>Characterization</td>
</tr>
<tr>
<td>Animal Safety &amp; Efficacy</td>
<td>Scale Manufacturing</td>
<td>Animal Testing</td>
</tr>
</tbody>
</table>

* The Catalyze Program does not support clinical trials or engagement with the FDA.

### Coordinating Center

**Funding**
Leverage federal investment with non-federal match

**Individualized Support**
Milestone-driven project management
Technical support to mitigate technical risk

**Coordinated Approach**
Seamless continuum of funding programs from validation through first-in-human trials

**Program Flexibility**
Evaluation and oversight
Identify and share best practices

For more information email NHLBI_Catalyze@mail.nih.gov
NHLBI Innovation Subject Matter Experts

Renée Arnold, PharmD
Entrepreneur-In-Residence
Health Economics Specialist

Gautam Prakash, PhD, JD
Intellectual Property Advisor

Luis Gutiérrez, MBA
Entrepreneur-In-Residence

Steve Flaim, PhD, MBA
Investor-In-Residence

Kwame Ulmer, MBA
Entrepreneur-In-Residence
Regulatory Specialist
NIH Support for Innovators

Chris Sasiela, PhD, RAC
Innovator Support Team Lead / Senior Regulatory Specialist
Small business Education and Entrepreneurial Development (SEED) Office
Preparing an application

– Sample Applications [NIAID]
  • https://www.niaid.nih.gov/grants-contracts/sample-applications#r43r44)

– Sample Applications [NIA]
  • https://www.nia.nih.gov/research/osbr/nia-small-business-sample-applications

– Understanding Per Review [CSR]
  • https://www.youtube.com/user/CSRNIIH
Online resources – Commercialization

Building a business

– Small Business Workshops [NIA]
  • https://www.nia.nih.gov/research/osbr/archived-small-business-events

– Business Finances [NIBIB]
  • https://www.nibib.nih.gov/entrepreneurial-finance-course

– Pitching Your Company [NHLBI]
  • https://www.youtube.com/watch?v=6QkIIDS_aPE&list=PL_nTiNjc6Gvksm4mQxmGh0iHM946PXEu0&index=3

– Intellectual Property Portfolios [NHLBI]
  • https://www.youtube.com/playlist?list=PL_nTiNjc6Gvksm4mQxmGh0iHM946PXEu0
PA-18-837
Administrative Supplement to Promote Diversity in Research and Development Small Businesses

Purpose: Improve the diversity of the research workforce
• Small Businesses with active small business awards (SBIR/STTR)
• Recruit and support individuals from underrepresented groups in health-related research

Career Level:
• Undergraduate
• Graduate
• Degree Holders
• Postdoctoral
• Developing Independent Career

Amount:
$5,000-100,000*
*Depending on candidate career level

Rolling Deadline
Concept to Clinic: Commercializing Innovation

• **C3i program**

Entrepreneurial education that teaches teams (innovator, entrepreneurial lead, mentor) methods to assess the commercial value, validate the market need, and develop a compelling pitch for their biomedical technologies.

• Available to academic and small business awardees.
• Available to NIH awardees
• Business, regulatory, payment, IP SME focused consults
• **Connect through your NIH Program Officer**

• Send us an email ([SEEDinfo@nih.gov](mailto:SEEDinfo@nih.gov))
• Info to include in your message:
  – Award number and NIH Program Officer name
  – Brief background about your project
  – Topic you want help with and specific questions
Questions