

NHLBI Product Development Support Services Request

Due Date: Monday, June 12, 2017 by 5:00PM ET

NHLBI is offering product development support that may include customized mentoring, pitch coaching, and registration support to attend an industry partnering meeting. Small Business Program awardees will be paired with a group of industry experienced mentors selected from NHLBI's national network of mentors and Entrepreneurs-in-Residence and receive support based on one of the following three tracks:

1. Product Development Mentoring

- 2 – 3 sessions over eight weeks with a team of mentors to focus on needs in topic areas such as: team construction, preclinical, regulatory, clinical development, finance, legal, marketing & sales, reimbursement, etc.

2. Pitch Coaching and Conference Support

- Pitch coaching by mentors and help preparing for partnering meetings
- 1 – 2 sessions over eight weeks with a team of mentors to focus on needs in topic areas such as: team construction, preclinical, regulatory, clinical development, finance, legal, marketing & sales, reimbursement, etc.
- Funding to register for an industry partnering or investor meeting (travel is not covered)

3. NHLBI Innovation Conference Mentoring and Life Sciences Summit Presentation

The NHLBI Innovation Conference is held in conjunction with the Life Sciences Summit, a premier early-stage investor and business development conference. Our support includes:

- Pre-conference pitch coaching and help preparing for partnering meetings
- Registration to the half-day NHLBI Innovation Conference featuring live pitch feedback sessions with expert mentors and discussions with industry insiders (Tuesday, October 31, 2017)
- Registration to the two-day Life Sciences Summit, which includes a 15 minute time slot to present to an audience of investors and pharmaceutical/MedTech leaders, 1-on-1 partnering meetings, panel discussions on topics relevant to early-stage companies, and a networking reception (Wednesday, November 1 and Thursday, November 2, 2017)

Eligibility

Any small business supported by an NHLBI SBIR/STTR award on or after June 1, 2015 is eligible to receive support. NHLBI will place companies in one of three tracks based on our assessment of your needs and available resources.

Note: Small businesses that delivered an oral presentation at the NHLBI Innovation Conference in 2016 are NOT eligible for the 2017 NHLBI Innovation Conference/Life Sciences Summit, but are eligible for the other services.

Instructions

1. Complete the Support Services Request and Company Profile.
2. E-mail the completed request and company profile, company logo, and an investor pitch deck (optional) to **rachel.weaver@nih.gov** by **5:00 PM ET on Monday, June 12, 2017**.

Note: If you have multiple NHLBI SBIR/STTR projects, please discuss the one that has the greatest clinical impact and commercial potential.

NHLBI Product Development Support Services Request

Company name: _____

Please indicate the track for which you would like to be considered.

☐ **Product Development Mentoring**

☐ **Pitch Coaching and Conference Support.** Please identify your desired conference(s) below.

Note: Conference(s) must include a pitch presentation and one-on-one networking opportunities, and must take place before September 30th, 2018.

Examples include RESI, MedTech Conference, BIO International Convention, and AdvaMed.

Showcase Conference(s): _____

☐ **NHLBI Innovation Conference Mentoring and Life Sciences Summit Presentation**

Please note that there are limited resources available for conference registration support and limited slots for the NHLBI Innovation Conference and Life Sciences Summit.

Team's Needs: Based on the track you selected, please provide a brief description (2-3 sentences) of the services you are most interested in:

Company Profile

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0740). Do not return the completed form to this address.

By submitting this application, you are providing permission to share its contents with external investors, potential strategic partners, and expert reviewers. You are also certifying that you have not included confidential information that you do not wish to share with non-NIH experts.

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Award Information

Provide the NIH SBIR/STTR award numbers (grant/contract) for the **one** (1) technology or product that you would like to present. If the award is an STTR grant, please indicate the name of the affiliated university.

Grant/Contract Number:

Affiliated University:

Company Information

Official Company Name:	
Alternative or Former Company Name(s):	
Corporate Structure:	<input type="checkbox"/> LLC <input type="checkbox"/> C-Corp <input type="checkbox"/> S-Corp <input type="checkbox"/> Sole Proprietorship
Company Address:	
Company Website:	
Current Number of Employees (total full-time equivalents [FTEs])	
Company CEO:	Name: Phone: E-mail:
Company Representative for Conference Participation:	Name and Title: Phone: E-mail:
Years company has been in business:	
Is the company a spinoff of another company?	Yes <input type="checkbox"/> No <input type="checkbox"/> If "Yes", please give name of parent company:
Is the company currently generating revenue?	Yes <input type="checkbox"/> No <input type="checkbox"/> If "Yes", please indicate dollar range of your company's sales revenues from products/services for the past year (include sales and licensing revenues) R&D Grant/Contracts: Sales from Products and Services: Licensing Fees and Royalties:

Executive Summary:

Please provide a brief description of the company and your technology. Describe the management team's experience in commercializing biomedical technologies, if any. **Please use no more than 250 words.**

Technology/Product Overview:

1. Select the one category that best describes the technology/product that will be presented:

- | | | |
|---|--|--|
| <input type="checkbox"/> Therapeutic – Small Molecule | <input type="checkbox"/> Therapeutic – Device | <input type="checkbox"/> Diagnostic - Software |
| <input type="checkbox"/> Therapeutic – Biologic (protein/peptide) | <input type="checkbox"/> Diagnostic – Device (Image-related) | <input type="checkbox"/> Companion Product |
| <input type="checkbox"/> Therapeutic – Biologic (cell) | <input type="checkbox"/> Diagnostic – Device (other) | <input type="checkbox"/> Health IT |
| <input type="checkbox"/> Therapeutic – Biologic (gene) | <input type="checkbox"/> Diagnostic – <i>In Vitro</i> | <input type="checkbox"/> Research Tool |
| <input type="checkbox"/> Therapeutic – Biologic (other) | <input type="checkbox"/> Diagnostic – Imaging Agent | <input type="checkbox"/> Production Tool |

2. Please describe the technology/product that was funded by the NIH.

Scientific Progress and Stage of Development:

Please check the appropriate boxes.

FDA Marketing Pathway: ☐ PMA ☐ 510(k) ☐ BLA ☐ NDA ☐ Not Applicable (*non-regulated product*)

FDA Application Status:

IND/IDE:	<input type="checkbox"/> Not yet submitted	<input type="checkbox"/> Submitted	<input type="checkbox"/> Approved
510(k)/PMA:	<input type="checkbox"/> Not yet submitted	<input type="checkbox"/> Submitted	<input type="checkbox"/> Cleared/Approved

Clinical Development Status: ☐ Preclinical ☐ Phase I ☐ Phase II ☐ Phase III ☐ Not Applicable

Device Class: ☐ 1 ☐ 2 ☐ 3 ☐ Not Applicable

1. Describe your product development progress (pre-clinical or clinical) and major technical objectives achieved to date.

2. Provide a brief overview of the regulatory strategy for the product under development. Describe current and future regulatory applications, approvals, and hurdles.

Intellectual Property:

1. List the most relevant issued and pending patent applications covering the product or technology (including provisional patent applications). If applicable, provide the name(s) of the institution(s) from which the IP was licensed and key non-confidential license terms.

2. List any trademarks or copyrights. *(Please enter numeric values where applicable.)*

	# Filed	# Approved	Subject matter or name of mark
Trademarks			
Copyrights			

3. Describe your company's strategy to generate and protect its intellectual property.

Market Description, Go-to-Market Strategy and Projected Revenues:

1. Describe the customer(s) and market segments for the product or service under development. Based on projected customer adoption, estimate the peak market size in dollars. Provide projected revenue and expected timeframes.
2. Explain how your product addresses an unmet need. What, if anything, do customers use now to meet this need?
3. Describe how you plan to commercialize the product. What is your "go-to-market" strategy (i.e. how will you get your product into customers' hands)?

Competitive Advantage:

1. Describe the competitive advantages of the product over both currently marketed products and products under development.
2. What are the anticipated barriers to adoption of your product?

Management Team:

List all current and pending management and key personnel in the company or collaborating with the company and describe their relevant expertise, experience, and previous success.

Business Development and Partnerships:

1. Are you currently seeking a partner to assist with the development and/or commercialization of the product?
☐ Yes ☐ No
2. If Yes, please indicate what kind of partnership(s) you are seeking (e.g., strategic, product development, manufacturing, distribution, etc.).
3. Describe any current or pending collaboration, development, license or strategic partnership agreements that the company has related to the product.
4. Please list any spin-offs from the company. If none, state "N/A".

Capital Raised To-Date:

List the source and amount of all capital that the company has raised since inception. In-kind support and its estimated value may also be included.

Date	Type	Source(s)	Amount

Future Investments:

1. Is the company currently seeking investments? ☐ Yes ☐ No
2. If Yes, describe the company's current fundraising activity and goals, including amount sought, intended use of funds, and potential sources of funding.

Company Milestones:

List major product development and commercial milestones achieved and/or expected over the next 24 months:

Milestone	Date

Publications, Presentations, and Awards:

List any significant past and pending publications, presentations and awards based on the company's technology.

Please limit publication list to 5 articles, however a link to the full publication history may be provided.

Conference Goals

What is your primary goal for attending and presenting at the conference?

- ☐ Seeking strategic partners (large business)
- ☐ Seeking investment
- ☐ Seeking scientific collaborators
- ☐ Customer discovery
- ☐ Increasing company visibility and exposure
- ☐ Gaining insight into competition and/or IP landscape
- ☐ Validating your business model
- ☐ Other, describe:

What would you like to get from participating in the event?