Phase I Commercialization Support:
I-Corps™ at NIH
Technical and Business Assistance (TABA) Needs Assessment

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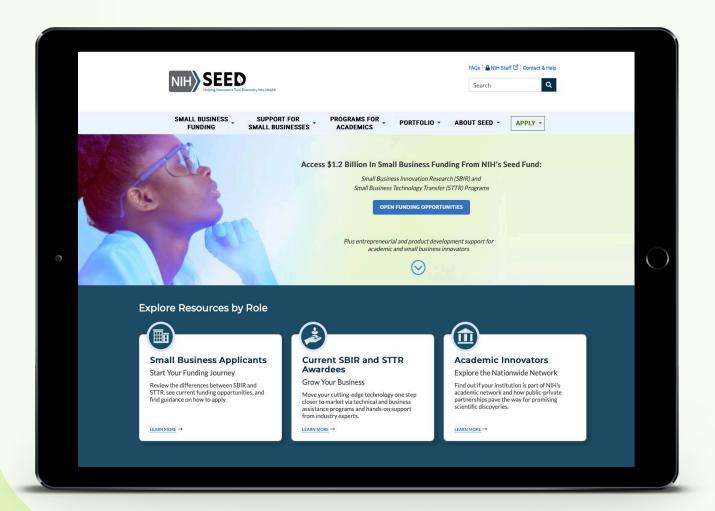
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HHS Small Business Program Lead

OFFICE OF EXTRAMURAL RESEARCH | OFFICE OF THE DIRECTOR | NATIONAL INSTITUTES OF HEALTH



# Small Business Program Website



http://seed.nih.gov



# I-Corps at NIH – A Phase I SBIR Supplement

FOA - <u>PAR-22-073</u>

Notice with FY 23 dates – NOT-CA-22-116

Application Deadline (Cohort 2): Wednesday, February 1st, 2023 5 PM your local time

More information: <a href="https://seed.nih.gov/l-Corps-at-NIH">https://seed.nih.gov/l-Corps-at-NIH</a>

Contact Email: icorps@mail.nih.gov



# What is I-Corps at NIH?

- Entrepreneurial Immersion Course for NIH and CDC funded small businesses
- Attendee teams conduct 100 customer discovery interviews over the period of 8 weeks to create a business model canvass for their NIH/CDC funded technology.

#### **Outcome Goals for I-Corps at NIH**

- Goal 1 To increase team's knowledge and understanding of the market opportunities. This is achieved through interviews with customers.
- Goal 2 To move the teams towards further funding success. Funding may be through non-federal state or equity based fundings or additional federal fundings.



# How will I-Corps at NIH help attendees?

### **Program for SBIR/STTR Phase I awardees to help:**

- Define the value proposition (e.g., clinical utility) <u>early</u> before spending millions saves time AND money
- Assess IP and regulatory risk before design and build
- Better understand core customers and the <u>specific</u> steps required for downstream commercialization
- Gather information essential to customer partnerships/ collaborations/ purchases before doing the science
- Identify financing vehicles before they are needed (helping to avoid the "Valley of Death")



# Eligibility

- Active Phase I SBIR/STTR Grant from participating ICs of NIH and CDC
- Phase I component of the Fast Track awards
- Only one supplement application per parent SBIR/STTR Phase I award is allowed under this FOA
- Phase I contractors with I-Corps at NIH option (must apply via acquisition offices to modify the existing contract)
- No Cost Extensions to maintain the eligibility (Only certain ICs)
- Phase II, Direct-To-Phase II, Phase II component of Fast Track grant are not eligible.



### Program Requirements

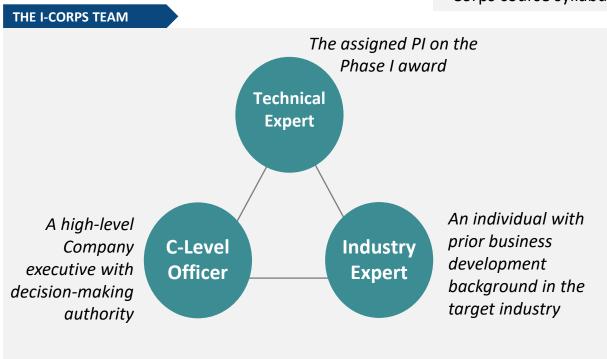
#### **REQUIREMENT**

Eligible SBIR/STTR grantees are required to assemble **3-member teams** that will work collaboratively to complete the activities and assignments required by the I-Corps curriculum.

#### **ELIGIBILITY**

• To be eligible, a company must have an ACTIVE Phase I SBIR or STTR grant from one of the 24 participating NIH and CDC Institutes and Centers

The predicate Phase I grant <u>must</u> have project and budget timelines that are active from application date through end of I-Corps course syllabus.





### Who can be on the team?

#### Is there flexibility in how the three required roles are filled on the I-Corps team?

Yes. For example, if the PD/PI (as listed in eRA) is also the CEO, then the PD/PI can be assigned the I-Corps role of "C-Level" and you can select a different senior level scientist to serve in the "TL" role.

In this example, consider Sue Scientist is the PD/PI (in eRA) on the predicate Phase I award; Sue is also the CEO of SBC, Inc. and will carry the role of C-Level on the I-Corps team. Sue recruits Robin Researcher, also of SBC, Inc., to be listed in eRA as a Co-Investigator and carry the role of Technical Lead on the I-Corps team. Finally, Evan Expert, an external advisor from Serial Entrepreneur, Inc. is listed in eRA as a Consultant to carry the role of Industry Expert on the I-Corps team.

Senior/Key Personnel	Organization	Role Category (in eRA)	I-Corps Team Role
Sue Scientist	SBC, Inc.	PD/PI	C-Level Executive
Robin Researcher	SBC, Inc.	Co-Investigator	Technical Lead/Expert
Evan Expert	Serial Entrepreneur, Inc.	Consultant	Industry Expert



### Program Format

THERAPEUTICS TRACK

DIAGNOSTIC TOOLS TRACK

THERAPEUTICS Expert

DIAGNOSTICS & HEALTH Expert

I-Corps Node Instructor

#### **COURSE FORMAT**

- 3-Day Kick-off Event
- 6 Weekly web classes
- 2-Day Lessons Learned

#### **LIFE SCIENCE TRACKS**

- Therapeutics
- Diagnostics/eHealth
- Medical Devices
- Teams are distributed among track "rooms"

#### **TEACHING TEAM**

- I-Corps Node Instructors
- Industry Domain Experts
- Curriculum tailored to life sciences



# NIH Expectations from the Participants

- Each team member commits 20-25 hour/week for the duration of 8 weeks for I-Corps related activities
- Fully participate in 3.5 days kick-off, 6 Wednesday webinars and 2-day close-out/finale (fully virtual)
- Conduct at least 100 customer discovery interviews
- Prepare and present a 2-minute video and a 10-minute lessonslearned presentation during the finale.



# Award Budget

The selected project teams receive grant supplement funding (up to \$55,000 total) to support customer discovery related activities –

- Course registration \$22000 (mandatory)
- Allowable expenses related to conducting customer discovery
  - Personnel time for team members (as appropriate)
  - Travel Conferences, trade shows, meetings <u>within</u> the cohort dates
  - Membership to disease specific foundations/societies
  - License fees for virtual meeting platforms
  - Indirect Fees
- Non-appropriate budget activities purchase of equipment (computers), marketing surveys and plans, IP filings etc.



### FY 23 Cohort Dates

### **Completely Virtual Cohort in FY23**

	Cohort 1 (Closed)	Cohort 2
Application Due Date	November 16, 2022	February 1, 2023
Phone Interview	January 9 - 10, 2023	March 6-7, 2023
Course Kick-off (Virtual)	March 6 - 9, 2023	May 8-11, 2023
Virtual Webinars	March 15, 2022 March 22, 2022 March 29, 2022 April 5, 2022 April 12, 2022 April 19, 2022	May 17, 2022 May 24, 2022 May 31, 2022 June 7, 2022 June 14, 2022 June 21, 2022
Course Close-out (Virtual)	April 24-25, 2023	June 26-27, 2023
Cohort Size	24 Teams	24 Teams



# Technical and Business Assistance (TABA) Needs Assessment



# Purpose of Technical and Business Assistance (TABA)

The 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



# TABA Programs

Phase I

#### **TABA Needs Assessment\***

Provides a third-party, unbiased assessment of areas that are critical to success in the competitive healthcare marketplace

Phase II

### **TABA Consulting Services\***

Available to limited number of awardees in the areas of Intellectual Property, Market Analysis, Regulatory Affairs, or Reimbursement Planning.

\*NIH ONLY

Phase I

### **TABA Funding**

Provides funding in grant to use your own vendors for Technical and Business Assistance

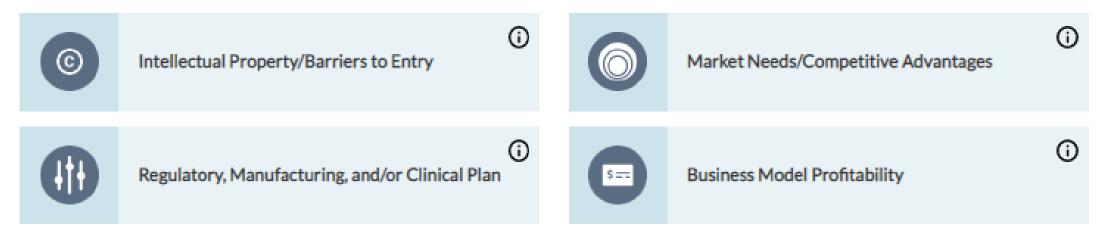


Phase II



### TABA Needs Assessment

Provides a third party, unbiased assessment (provided by <u>RTI Innovation Advisors</u>)
to help small businesses identify their most pressing product development needs



- Suggests highest priority steps to improve the commercial potential
- Supports companies developing all types of technologies





# TABA Needs Assessment: Eligibility

SBIR and STTR Phase I and Phase I Fast-Track recipients that have had an active Phase I grant, cooperative agreement, or contract within two years of request



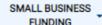
Projects that received TABA Funding (or a Niche Assessment) in the Phase I are **ineligible** 

Projects can participate in other Support Programs (e.g., I-Corps or C3i) and remain eligible



### Request Process

- Review the <u>sample report</u> BEFORE requesting: Structure and scope are fixed
- Open all year
- MUST request an assessment at https://seed.nih.gov/support-for-awardees/taba-needs-assessment
- Requests must be complete
- NIH will confirm eligibility
- Notification of status within 60 days of submission





PROGRAMS FOR ACADEMICS

PORTFOLIO -

ABOUT SEED

Home / Support for Small Businesses / NIH's Technical and Business Assistance Program / Technical and Business Assistance (TABA) Needs Assistance

#### Technical and Business Assistance (TABA) Needs Assessment

The TABA Needs Assessment Report provides a third party, unbiased assessment of a Phase I project's progress in to areas that are critical to success in the competitive healthcare marketplace. There is no cost for this report and the tiparticipation is minimal.

The Needs Assessment Report helps companies strategize for the project's next steps. It analyzes the current state of and identifies strengths and weaknesses across four categories.



Intellectual Property/Barriers to Entry



Market Needs/Competitive



Regulatory, Manufacturing, and/or Clinical Plan



Business Model Profitability

The information in each report will be tailored to the participating company's project, but the structure and scope of View a sample Needs Assessment Report

#### Eligibility

Your company is eligible to participate if your Phase I NIH SBIR or STTR (grant, contract, or Fast-Track)

- Is active or was active within the past two years AND
- Was not awarded TABA funding within the Phase I award budget AND
- · Has not already received a TABA Needs Assessment Report or NICHE Assessment for the same Phase I project

Questions? Email seedinfo@nih.gov ₪.

Request a Needs Assessment Report

The TABA Needs Assessment Report is provided by <u>RTI Innovation Advisors</u> through an NIH contract. Recommental Innovation Advisors do not represent the views of NIH or NIH staff.



### Needs Assessment Process

Company Notification

- Must Confirm:
  - Reviewed and acknowledged the deliverable (<u>sample report</u>)
  - Ready to proceed
  - Appropriate contact

RTI Performs Analysis

- Initial Phone interview within two months
- RTI works with company to verify information

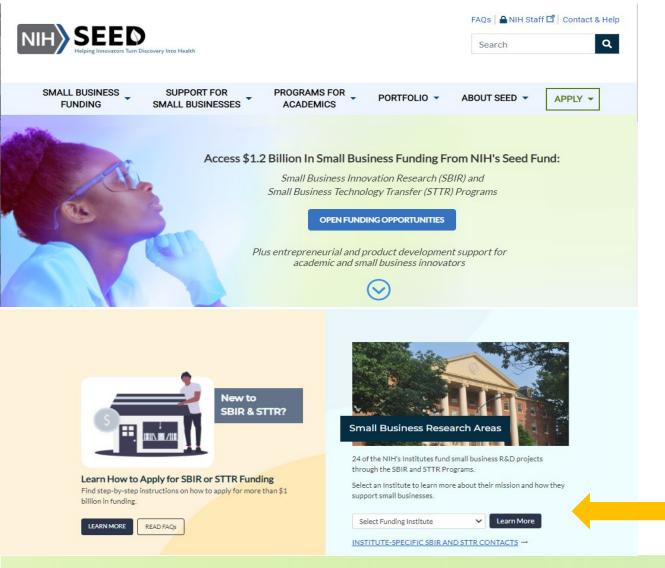
RTI Delivers
Draft

- Delivered within 3-4 months
- Company has 10 business days to review for accuracy and ask questions
- RTI will have 10 business days to incorporate questions/feedback

RTI Delivers Final Needs Assessment Report



# Most Important Piece of Advice



#### Talk to a Program Officer

List of SBIR Program Managers: <a href="https://seed.nih.gov">https://seed.nih.gov</a>

#### Not sure who to contact?

Research Portfolio Online Reporting Tools (RePORT): <a href="https://report.nih.gov/">https://report.nih.gov/</a>

Email: <u>SEEDinfo@nih.gov</u>

Questions?



### Connect with SEED



Online

http://seed.nih.gov/



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SEEDinfo@nih.gov



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