

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing at any time. Refusal to participate will not affect your benefits in any way. The information collected will be kept private to the extent provided by law. Names and other identifiers will not appear in any report. Information provided will be combined for all participants and reported as summaries. You are being contacted by email to complete this form so that NIH institutes that participated in the CARE program can connect you with the FDA to receive feedback on your regulatory questions.

Public reporting burden for this collection of information is estimated to average 60 minutes 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 (0925-0766). Do not return the completed form to this address.

# NIH Small Business Program with FDA CARE – Connecting Awardees with Regulatory Experts

## Application Form for NIH Small Businesses

Thank you for your interest in the CARE Program. Please complete one application form per applicable project. To be eligible to participate, your small business:

- Received a Phase I or II SBIR/STTR award from the National Institutes of Health (NIH) in fiscal year 2022 or later
- Has a technology that falls under the regulatory authority of the U.S. Food and Drug Administration (FDA)
- Has not met/discussed this product with FDA or participated in the CARE Program previously for this product
- Has visited this website to answer basic regulatory questions [CARE Regulatory Program - NCI \(cancer.gov\)](https://www.cancer.gov/care)
- Agrees to provide feedback in a brief survey at the end of the program
- Acknowledges this application will be shared with NIH and FDA

### Instructions:

- Please note the text space limits within the application fields.
- At this time, NHLBI, NIA, NIBIB, and NICHD are accepting CARE applications for CBER- and CDRH-regulated technologies only.
- All forms must be submitted by March 8, 2024.
- Email the completed form to the point of contact listed below at the NIH Institute that issued the award.

National Cancer Institute  
 National Heart Lung and Blood Institute  
 National Institute of Aging  
 National Institute of Biomedical Imaging and Bioengineering  
 Eunice Kennedy Shriver National Institute of Child Health and Human Development

[swamy.tripurani@nih.gov](mailto:swamy.tripurani@nih.gov)  
[stephanie.davis3@nih.gov](mailto:stephanie.davis3@nih.gov)  
[rajesh.kumar3@nih.gov](mailto:rajesh.kumar3@nih.gov)  
[nibib-sbir@mail.nih.gov](mailto:nibib-sbir@mail.nih.gov)  
[antonello.pileggi@nih.gov](mailto:antonello.pileggi@nih.gov)

### Award Information

NIH Grant Award Number for this product/technology:  
 NIH Program Officer:

### Company Information

Company name:  
 Contact person for this application:  
 Title/Role:  
 Email:  
 Phone:

Indicate the technology area(s) that describe the SBIR/STTR-funded technology (select all that apply):

- |                   |                             |   |
|-------------------|-----------------------------|---|
| Small molecule    | Surgical or ablative device | Imaging agent                           |
| Biologics/vaccine | Hospital device             | Imaging device                          |
| Cell/gene therapy | Drug delivery device        | Bioinformatics/health IT/digital health |
|                   | In vitro diagnostic         |   |

Indicate the development stage of the SBIR/STTR-funded technology:

- |   |                        |
|---|------------------------|
| Early stage (in vitro or untested prototype)          | Ready to commercialize |
| Ongoing (in vivo testing or refining an early design) | Commercial product     |
| Testing in a clinical setting                         |                        |

Technology name (please provide a short, ten words or fewer, description of your technology):

What is the unmet medical need that your technology addresses? How does your technology solve the problem? Limit your response to 500 characters maximum, including spaces.

Does your potential technology fall under FDA's regulatory authority?\*

- Center for Biologics Evaluation and Research (CBER)
- Center for Drug Evaluation and Research (CDER)
- Center for Devices and Radiological Health (CDRH)
- Unsure

\*Note: At this time, NHLBI, NIA, NIBIB, and NICHD are accepting CARE applications for CBER- and CDRH-regulated technologies only.

Has your company met with FDA previously to discuss the regulatory strategy for this technology?

- Yes
- No
- Unsure

If yes, please provide approximate date and type of meeting.

Has your company attended any educational workshops, webinars, or other events hosted by FDA in the past 2 years?

- Yes
- No
- Unsure

If yes, please list the name(s) and approximate date(s).

Does your company currently have access to a regulatory consultant?

- Yes
- No
- Unsure

If yes, have you discussed your questions on page 5-6 with the consultant?

Are you familiar with any of FDA's industry education websites (i.e., CBER/CDER/CDRH Learn)?

- Yes
- No
- Unsure

Are you familiar with CBER's Manufacturers Assistance and Technical Training Branch ([Manufacturers Assistance and Technical Training Branch \(MATTB\) | FDA](#))?

- Yes
- No
- Unsure
- Not applicable to my technology

Are you familiar with CDER's Oncology Regulatory Expertise and Early Guidance Initiative (<https://www.fda.gov/about-fda/oncology-center-excellence/oncology-regulatory-expertise-and-early-guidance-oreeg>)?

- Yes
- No
- Unsure
- Not applicable to my technology

Are you familiar with CDRH's Early Payor Feedback Program (<https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force/#2>)?

- Yes
- No
- Unsure
- Not applicable to my technology

Are you familiar with CDRH's Regulatory Science Tools Catalog to help assess new medical devices (<https://www.fda.gov/medical-devices/science-and-research-medical-devices/catalog-regulatory-science-tools-help-assess-new-medical-devices>)?

- Yes
- No
- Unsure
- Not applicable to my technology

Are you familiar with CDRH's Medical Device Development Tools (MDDT) Program? The MDDT Program aims to facilitate regulatory decision making by qualifying tools that support safety, effectiveness, or performance assessments of medical devices. (<https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-development-tools-mddt>)

- Yes
- No
- Unsure
- Not applicable to my technology

**Please include a summary of background information on your technology. Limit your response to one page maximum.**

PLEASE USE THIS WEBSITE TO FIND BASIC INFORMATION BEFORE YOU SUBMIT YOUR QUESTIONS TO THE FDA: [CARE Regulatory Program - NCI \(cancer.gov\)](https://www.fda.gov/care)

**Please state up to five regulatory questions you have for FDA. Please number each question separately (i.e., do not include multi-part questions).**

**Please include any relevant information specific to each question. This will allow FDA to provide a more informed response to your questions.**

**The CARE Program is intended to provide small businesses with product type information from FDA. This program does not replace any formal or informal meetings encouraged or required by FDA. Information provided as part of this program will not be used by FDA for any preliminary or future decision-making regarding the technology.**

1. Question

Information

2. Question

Information

3. Question

Information

4. Question

Information

5. Question

Information