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

Application Form for NCI and NHLBI 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 Cancer Institute (NCI) or National Heart, Lung, and Blood Institute (NHLBI) in fiscal year 2021 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)
- ☐ Agrees to provide feedback in a brief survey at the end of the program
- ☐ Acknowledges this application will be shared with NCI, NHLBI, and FDA

☐ I have reviewed the eligibility requirements listed above and meet all the criteria.

Please note the text space limits within the application fields. All forms must be submitted by March 10, 2023. Email completed form to the NIH Institute that issued the SBIR/STTR award: NCI NCIsbirEvents@mail.nih.gov or NHLBI nhlbi_sbir@mail.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
- ☐ Biologics/vaccine
- ☐ Cell/gene therapy
- ☐ Surgical or ablative device
- ☐ Hospital device
- ☐ Drug delivery device
- ☐ In vitro diagnostic
- ☐ Imaging agent
- ☐ Imaging device
- ☐ Bioinformatics/health IT/digital health

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

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

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 is supporting 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)

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