

Application

Subject Line: Got a question for FDA? NCI SBIR can help.

Dear SBIR/STTR Awardee,

The NCI SBIR Development Center would like to invite you to participate in a **free program CARE – Connecting Awardees with Regulatory Experts**. The purpose of the CARE Program is to provide NCI SBIR/STTR-funded small businesses with an **additional avenue for informal communication with FDA** about their technologies.

If you are in the early stages of developing a technology that will be regulated by FDA (or you are unsure!) and have regulatory questions, consider taking advantage of this free opportunity to get feedback from the FDA.

*Current NCI awardees that are developing a technology under the regulatory authority of **any FDA Center (i.e., CBER, CDER, or CDRH)** and have not met with FDA previously are eligible to participate.*

Applications for the CARE pilot program will go through the following process:

- NCI SBIR Development Center will collect applications and provide to the appropriate FDA Center (i.e., CBER, CDER, or CDRH).
- CBER, CDER, or CDRH will review the regulatory questions and provide guidance on the appropriate group at FDA that can answer the questions.
- Regulatory questions could be answered by FDA on an individual basis by a small business information office or an FDA Reviewer.
- For regulatory questions that require more in-depth review, a pre-submission meeting could be recommended.

This program is intended for early-stage companies that have not participated in CARE previously. Note, the CARE program does not replace any formal or informal meetings encouraged or required by FDA.

To participate:

- Visit NCI SBIR's regulatory resources webpage and check if your questions have already been answered here <https://sbir.cancer.gov/resources/fda-resources>.
- Complete the attached application form and email it to NCISbirEvents@mail.nih.gov.

Feedback Survey

Subject Line: NCI SBIR CARE program: please complete 2 min survey

Thank you for participating in the NCI CARE Program this year! I'd appreciate your feedback on what was/wasn't helpful to your company.

We appreciate you taking a 4-question, multiple choice survey found at this link:

<https://www.surveymonkey.com/r/LSBV5VF>