2024 NIH Small Business Program with FDA CARE – Connecting Awardees with Regulatory Experts

OMB No.: 0925-0642
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The Public Health Service Act, Section 411 (42 USC 285a) allows collecting this information. The 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 NCI can improve the program.

The public reporting burden for this information collection is estimated to average 3 minutes per response, including reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. An agency may not conduct or sponsor, and a person is only required to respond to, a collection of information if it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0642). Do not return the completed form to this address.

All questions are optional and you may exit the survey at any time.

1. Company Information

Company Name	
Contact Person	
Title/Role	
Email	

2. Please indicate the extent to which you agree with the following. Participation in the CARE Program helped our team…

	Strongly Agree	Agree	Disagree	Strongly Disagree
Learn and/or confirm the FDA Center (CBER, CDER, CDRH) or Office that will regulate our technology	○	○	○	○
Begin developing the regulatory strategy for our technology	○	○	○	○
Plan the next regulatory step(s) for our technology	○	○	○	○
Clarify and/or confirm the appropriate regulatory path for our technology	○	○	○	○
Gain a better understanding of the process to contact FDA for a meeting request	○	○	○	○
Find information on FDA’s website related to a particular regulatory topic	○	○	○	○
Understand how to contact an FDA office that provides free resource assistance to industry (i.e., MATTB, SBIA, or DICE)	○	○	○	○

3. Please indicate the extent to which you agree with the following. Following the CARE Program, our team plans to…

	Strongly Agree	Agree	Disagree	Strongly Disagree
Contact an FDA office via phone or email that provides free resource assistance to industry (i.e., MATTB, SBIA, or DICE)	○	○	○	○
Watch an FDA webinar(s) on a particular regulatory topic	○	○	○	○
Read an FDA guidance(s) on a particular regulatory topic	○	○	○	○
Access an FDA website to learn more on a particular regulatory topic	○	○	○	○
Submit a meeting request to FDA to discuss regulatory strategy (e.g., INTERACT meeting, pre-IND meeting, pre-submission meeting, etc.)	○	○	○	○
Hire a regulatory consultant or other personnel to help with the team's regulatory strategy	○	○	○	○
Schedule a free regulatory consultation with an NIH SEED Regulatory Specialist at https://seed.nih.gov/product-development-support/consulting/regulatory-consultation or Other Entrepreneur-in-Residence (EIR) Expert at NIH	○	○	○	○

4. Please indicate the extent to which you agree with the following. Our team…

	Strongly Agree	Agree	Disagree	Strongly Disagree
Found the CARE Program useful	○	○	○	○
Found the NCI SBIR FDA resources website useful https://sbir.cancer.gov/resources/fda-resources	○	○	○	○
Received information from the CARE Program that will affect our future SBIR/STTR specific aims	○	○	○	○
Would recommend the CARE Program to other companies	○	○	○	○

5. We welcome any additional feedback or comments you wish to provide.