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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 (0925-0648). Do not return the completed form to this address.

## 2023 NIH Small Business Program with FDA CARE - Connecting Awardees with Regulatory Experts

### \* 1. Company Information

Company Name	<input type="text"/>
Contact Person	<input type="text"/>
Title/Role	<input type="text"/>
Email	<input type="text"/>

### \* 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Begin developing the regulatory strategy for our technology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plan the next regulatory step(s) for our technology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Clarify and/or confirm the appropriate regulatory path for our technology	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Gain a better understanding of the process to contact FDA for a meeting request	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Find information on FDA's website related to a particular regulatory topic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Understand how to contact an FDA office that provides free resource assistance to industry (i.e., MATTB, SBIA, or DICE)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

\* 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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Watch an FDA webinar(s) on a particular regulatory topic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Read an FDA guidance(s) on a particular regulatory topic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Access an FDA website to learn more on a particular regulatory topic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Submit a meeting request to FDA to discuss regulatory strategy (e.g., INTERACT meeting, pre-IND meeting, pre-submission meeting, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hire a regulatory consultant or other personnel to help with the team's regulatory strategy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Schedule a free regulatory consultation with an NIH Regulatory Specialist <a href="https://seed.nih.gov/support-for-small-businesses/commercialization-enhancement-programs/entrepreneurial-development#innovator-consultations">https://seed.nih.gov/support-for-small-businesses/commercialization-enhancement-programs/entrepreneurial-development#innovator-consultations</a> or <a href="https://www.nhlbi.nih.gov/about/divisions/division-extramural-research-activities/office-translational-alliances-and-coordination">https://www.nhlbi.nih.gov/about/divisions/division-extramural-research-activities/office-translational-alliances-and-coordination</a>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

\* 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Found the NCI SBIR FDA resources website useful <a href="https://sbir.cancer.gov/resources/fda-resources">https://sbir.cancer.gov/resources/fda-resources</a>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Received information from the CARE Program that will affect our future SBIR/STTR specific aims	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Would recommend the CARE Program to other companies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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