

Appendix B: Demographic Questionnaires

RESEARCH SPONSOR		
No.	Question	Answer
1.	Which best describes the type of organization with which you are currently affiliated? [Read aloud responses] <i>Select only one</i>	<input type="checkbox"/> Pharmaceutical or medical device industry <input type="checkbox"/> Federal government agency <input type="checkbox"/> Clinical research organization <input type="checkbox"/> Other (please specify): _____
2.	What type of product or products does your company develop? [Read aloud responses] <i>Select all that apply</i>	<input type="checkbox"/> Drugs, either therapeutic or preventive <input type="checkbox"/> Vaccines <input type="checkbox"/> Devices <input type="checkbox"/> Biologics <input type="checkbox"/> Combination products (e.g., drug-devices) <input type="checkbox"/> Other (please specify): _____
3.	What is your current role in clinical research and development?	
4.	How many years have you been in this role?	_____
5.	How many years in total have you been engaged in clinical research?	_____
<p>For the following four questions, please consider the clinical research that you have personally been involved in at your company.</p> <p>When responding, include only research where mobile devices were used to <i>collect</i> data.</p> <p>This can be objective or patient-reported data.</p> <p>We are not interested in the use of mobile devices for recruitment, retention, and informed consent.</p>		
6.	How many studies, if any, have you been involved in that assessed the feasibility of using a mobile device to collect data? Meaning, the purpose of the study was to test the device in some way. It was not used to measure endpoints in a clinical study. For example, a study to validate the device or to assess patient preferences with using the device.	_____
7.	How many observational or pilot studies, if any , have you been involved with that used a mobile device to collect data related to study endpoints in a clinical study?	_____

RESEARCH SPONSOR		
No.	Question	Answer
8.	How many FDA-regulated clinical trials , if any, have you been involved with where a mobile device was used to collect data related to the study objectives?	_____
9.	Please describe any other clinical studies where you have used a mobile device in some way.	
10.	In these studies, what types of mobile devices were used? [Read aloud responses] <i>Select all that apply</i>	<input type="checkbox"/> Movement sensor. For example, an accelerometer, actigraph or gyroscope. This can be medical grade or installed in consumer-grade device such as a smartphone. <input type="checkbox"/> Smart phone application such as ResearchKit <input type="checkbox"/> Biosensor. For example, a continuous glucose monitor, heart rate monitor, or biochemistry monitors. Specify: _____ <input type="checkbox"/> Pressure sensor <input type="checkbox"/> Video camera <input type="checkbox"/> Audio sensor <input type="checkbox"/> GPS (Global Positioning System) <input type="checkbox"/> Other (specify) _____

INVESTIGATOR		
No.	Question	Answer
1.	Which best describes the type of organization with which you are currently affiliated? [Read aloud responses] <i>Select only one</i>	<input type="checkbox"/> Academic institution/academic health system with research and education responsibilities <input type="checkbox"/> Community or private practice with a primary clinical responsibility <input type="checkbox"/> Hospital with no affiliated academic institution <input type="checkbox"/> Dedicated research site with no affiliated clinical practice responsibility <input type="checkbox"/> Pharmaceutical or medical device industry <input type="checkbox"/> Federal government agency <input type="checkbox"/> Other (please specify): _____

INVESTIGATOR		
No.	Question	Answer
2.	<p>What is your role on your current clinical trials that use mobile devices?</p> <p>[Read aloud responses]</p> <p><i>Select all that apply</i></p>	<input type="checkbox"/> PI <input type="checkbox"/> Sub-PI or Co-PI <input type="checkbox"/> Other (please specify): _____
3.	<p>How many years have you served as a PI, sub-PI, or co-PI on clinical trials?</p>	_____
4.	<p>What type of product or products do you investigate?</p> <p>[Read aloud responses]</p> <p><i>Select all that apply</i></p>	<input type="checkbox"/> Drugs, either therapeutic or preventive <input type="checkbox"/> Vaccines <input type="checkbox"/> Devices <input type="checkbox"/> Biologics <input type="checkbox"/> Combination products (e.g., drug-devices) <input type="checkbox"/> Other (please specify): _____
<p>For the following four questions, please consider the clinical research that you have personally been involved in.</p> <p>When responding, include only research where mobile devices were used to <i>collect</i> data.</p> <p>This can be objective or patient-reported data.</p> <p>We are not interested in the use of mobile devices for recruitment, retention, and informed consent.</p>		
5.	<p>How many studies, if any, have you been involved in that assessed the feasibility of using a mobile device to collect data? Meaning, the purpose of the study was to test the device in some way. It was not used to measure endpoints in a clinical study. For example, a study to validate the device or to assess patient preferences with using the device.</p>	_____
6.	<p>How many, if any, observational or pilot studies have you been involved with that used a mobile device to collect data related to study objectives in a clinical study?</p>	_____
7.	<p>How many, if any, FDA-regulated drug trials have you been involved with where a mobile device were used to collect data related to the study objectives?</p>	_____

INVESTIGATOR

No.	Question	Answer
8.	<p>In any of these studies, what types of mobile devices were used?</p> <p><i>[Read aloud responses]</i></p> <p><i>Select all that apply</i></p>	<ul style="list-style-type: none"> <input type="checkbox"/> Movement sensor. For example, an accelerometer, actigraph or gyroscope. This can be medical grade or installed in consumer-grade device such as a smartphone. <input type="checkbox"/> Smart phone application such as ResearchKit <input type="checkbox"/> Biosensor. For example, a continuous glucose monitor, heart rate monitor, or biochemistry monitors. Specify: _____ <input type="checkbox"/> Pressure sensor <input type="checkbox"/> Video camera <input type="checkbox"/> Audio sensor <input type="checkbox"/> GPS (Global Positioning System) <input type="checkbox"/> Other (specify) _____