

## INVESTIGATOR & SPONSOR INTERVIEW GUIDE

### Mobile Devices in Clinical Research: Scientific and Technological Considerations and Challenges

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|--|---|
| 1. Interviewer Name                                      |   |
| 2. Participant ID#                                       |   |
| 3. Interview Date (dd/mm/yyyy)                           | _ _ _ / _ _ _ / _ _ _ _ _   |
| 4. Participant agrees for interview to be audio recorded | Yes..... <input type="checkbox"/><br>No..... <input type="checkbox"/> |
| 5. Time Interview Began (hhmm-24hr clock)                | _ _ _ _ _   |
| 6. Time Interview Ended (hhmm-24hr clock)                | _ _ _ _ _   |

- Step 1:** Complete Q1-3 above before calling the participant.
- Step 2:** Once you connect with the participant, introduce yourself; thank participant for taking part in the interview.
- Step 3:** Read Section A below to participant.
- Step 4:** Ask permission to record interview; tick appropriate box in Q4 above.
- Step 5:** Turn on audio recorder if acceptable, document time interview begins in Q5 above, and conduct interview.
- Step 6:** At the end of the interview, thank the participant and ask if she/he has any further questions; document time interview ended in Q6 above.
- Step 7:** To acknowledge their contribution, ask if the participant is interested in being listed as a participant in this study (name and company) in the publication of these data and the recommendations document (data will not be linked specifically to the participant); if yes, document appropriately (Appendix E).
- Step 8:** Ask if the participant is interested in being re-contacted to receive a summary of the study results; if yes, document appropriate contact information for follow-up (Appendix E).
- Step 9:** Ask if the participant is interested in being re-contacted about CTTI's future Mobile Clinical Trials research and project activities (Appendix E).

#### SECTION A: Information about the study

- Hello, thank you for taking time out of your busy schedule to speak with me today. My name is [Name], and I am a \_\_\_\_\_ with the Clinical Trials Transformation Initiative. Is now still a good time to talk?
- As you are well aware, the use of mobile devices within clinical research is rapidly growing. Yet, their use within phase 3 clinical trials, and particularly FDA-regulated trials, has not yet reached its full potential. This may be due in part to concerns among research sponsors and investigators about the

multitude of scientific and technological considerations and challenges that must be addressed and overcome before mobile devices can be successfully used in clinical trials.

- The Clinical Trials Transformation Initiative – referred to as CTTI – is developing evidence-based recommendations to address this issue. We are interested in hearing your thoughts on how scientific and technological challenges in using mobile devices for data capture in FDA-regulated drug trials can be addressed and overcome.
- We are also interested in hearing more about the work you have done in this area and particularly the issues you came across as you integrated mobile devices into your clinical studies.
- To be clear, as we discuss “mobile devices” throughout this interview, we are referring to mobile applications and remote sensor devices, including both consumer and medical grade devices.
- Also, for the purpose of this interview, we will define the use of these mobile devices in clinical trials as the use of mobile technology to collect objective or patient-reported data during a clinical trial. We are not focused on the use of mobile devices for recruitment, retention and informed consent.
- There are no right or wrong answers to the questions I will ask, only opinions. We want to hear about the considerations you made as you designed your studies and your experiences before, during and after conducting the trials. Please feel free to share your candid thoughts to the questions that I ask you. It’s very helpful to hear your point of view.
- As described in the informational sheet provided to you earlier, participating in this interview is voluntary. You can choose not to answer a question or you can stop participating at any time. We do not think there will be any personal risks or benefits from the interview today. However, there is a risk of loss of confidentiality. This means that people outside the study team could learn what you said in the interview. But we think this is unlikely because we do many things to protect the information you tell us such as storing your data on secure servers.
- If you agree, I would like to audio record the interview because I want to make sure I don’t miss any of your comments. If you don’t want the interview audio recorded, I will take detailed notes during the interview instead.
- The interview will take roughly 1 hour. Information about who to contact if you have questions about the study, including the Duke IRB, can be found in the informational sheet.
- Do you have any questions for me so far about the interview?

***[If yes, answer the participant’s questions then proceed with the completing the demographic form.]***

***[If no, proceed with the completing the demographic form.]***

Is it okay if I turn on the audio recorder now?

***[If yes, begin audio recording now.]***

*[If no]* That's okay, I'll take detailed notes as we talk.

Ok, let's get started!

## **SECTION B: Background information**

I'd like to begin our discussion by getting a better understanding of how you've used mobile devices in a clinical study.

*[For the following question refer to information shared in the Demographic Questionnaire.]*

1. *[If used mobile devices in only one study]* You mentioned earlier that you used a \_\_\_\_\_ *[add device use]* in a *[add study type]*.

*[If used mobile devices in more than one study]* Of the studies you mentioned where mobile devices were used, can you please choose one that we can primarily talk about during the interview. This can be the trial that you learned the most from. ***But, as we talk about these topics, feel free to bring in experiences from your other studies whenever applicable.***

Can you tell me more about that study and how that device was used?

### ***Follow-up as necessary:***

- a. What therapeutic area/s was the study addressing?
- b. What were the study's objectives?
- c. Who used the mobile devices during the study? (i.e., patient, caregiver)
- d. What source data did you gather from the device?
- e. How was the mobile device used by the participant to collect data? (i.e., objective data, subjective data)
- f. How were the data used in the study (i.e., to answer primary or secondary objectives, exploratory)
- g. What were the endpoints derived (calculated) from the device?

During our interview, I'd like to ask you about decisions you, or your team, made regarding the use of mobile technology throughout your trial. I'm going to list various steps involved in conducting trials where sponsors and investigators need to make important decisions about the use of mobile technology and I'd like you to tell me which you have the most experience with or interest in talking about today.

How much were you involved in the...

- Planning of the trial**, including how the uses of particular devices were selected, and how the devices were calibrated and data validated?
- The **implementation of the trials**, including training participants and staff, ensuring data attribution, data security, and dealing with technical difficulties throughout the study?
- The **monitoring of mobile data**, including internal and external data monitoring?
- Data analysis**, including development of a data analysis plans and interpreting big datasets or meaningfulness of new endpoints?
- And finally, **reporting data**, particularly reporting data back to participants?

Where would you like to begin?

***[Skip to the appropriate section of the guide depending on the participant's selection. Once that section is thoroughly discussed, either use best judgment as to which section to move to next or ask the participant to self-select another section to discuss.]***

### **SECTION C: Trial planning**

I want you to think back to decisions you have made while designing and planning that study – as well as other studies you have conducted where you have used mobile devices for data capture. I particularly want to know how the decision to use mobile device in the trial came about.

2. ***[Device decision]*** Generally speaking, why did you decide to use a mobile device to gather data in this study rather than using traditional data collection approaches? What I mean by “traditional” is other instruments or measurements that have been used in clinical practice or in research to gather data for this particular therapeutic area.
3. Given that, why did you select the particular mobile device that you did?
  - a. During your decision-making processes, what considerations did your team discuss, if any, about whether to use a consumer-grade or medical-grade device? By consumer grade, I mean a general wellness product that is available to consumers and is not regulated by the FDA as a medical device.
  - b. What factors influenced the final decision on the type of device to use?
  - c. What considerations, if any, did your team have on allowing participants to use their own mobile devices?
    - i. What factors influenced the final decision?
  - d. ***[If not BYOD]*** How were the devices obtained? ***[Probe about whether multiple suppliers offered the device]***
    - i. How was the final decision made to work with the specific supplier of the device?
  - e. Looking back on it, what would you have done differently?
  - f. What suggestions do you have for other investigators/research sponsors on selecting a device to use in their clinical research?
4. ***[Device validation]*** What steps did you take to validate the device? By validation I mean that the device is able to collect the requested data and that these data do not vary among other devices or over time.

#### ***Follow-up if applicable and as necessary:***

- a. Was the device tested under varying conditions?
  - i. ***[If yes]*** How so? ***(Probe about under varying conditions, such as different temperatures and battery life, and under different use case scenarios, such as on different parts of the body)***
- b. How did you ensure that all devices were collecting consistent data across all participants in your study?
- c. Were the data collected from the device compared to data collected from traditional measures?  
***[If yes]***
  - i. Why was this done?

- ii. How was this done?
  - d. Were there any challenges that you faced when validating the device?
    - i. [If any] How were these addressed?
  - e. What, if anything, would you do differently if you had the option to do it all over again?
  - f. What suggestions do you have for other investigators/research sponsors on validating their device?
5. **[Device calibration]** In your study, who was responsible for ensuring that the mobile devices were calibrated? By this I mean that the device is adjusted to match or conform to a dependably known and unvarying measure, if one exists.
- Device manufacturer
  - Investigator
  - Sponsor
  - Patient
- a. How was that decision made?
  - b. **[If applicable]** What was done to calibrate the devices? **[Probe about any assistance from the supplier; usefulness of the device's user manual]**
    - i. **[If done]** When was this done during your study? **[Probe: at the beginning or routinely throughout the study]**
  - c. What, if anything, would you do differently if you had the option to do it all over again?
  - d. What suggestions do you have for other investigators/research sponsors on calibrating their device?
6. **[Device Management]** You explained **[insert from above]** was responsible for device calibration. Who was responsible for the more day to day management of the device during your study? (e.g., routine maintenance of the mobile device)
- a. How did you manage manufacturer upgrades to the device, software or operating system, if any, during the course of the study?

This is all very helpful information. I'd now like us to discuss how the mobile device was actually used as a data collection instrument in your clinical, but before we move on, is there anything else that you'd like to share with me regarding why you planned to use a mobile device in a clinical study and how you prepared the devices or study design to utilize the device?

#### **SECTION D: Implementation**

So now I would like you to recall how the mobile device was used in your trial.

7. **[Data collection]** What concerns did the team have collecting data using a mobile device? **[After each issue is mentioned, probe: Anything else?]**

**Follow up for each issue identified:**

- a. How did you address this issue?
- b. What steps did you take to ensure the data collected by the device were in the right units or format to link correctly with the endpoint?
- c. What would you have done differently if you could?

- d. What suggestions do you have for other investigators/research sponsors?
8. **[Device training]** What steps did you take to ensure that participants used the device properly?  
**[Probe: how this was ensured throughout the life of the study.]**
- Follow-up as necessary:**
- a. How did you approach training patients and/or caregivers in using the device for the study?
  - b. What concerns, if any, did you hear from participants about the use of the mobile device?
  - c. Looking back on it, what would you have done differently, if anything?
  - d. What suggestions do you have for other investigators/research sponsors?
9. **[Data attribution]** What steps did you take to ensure user authentication and access control to the device? In other words, how did you ensure that the intended participant was the creator of the data?
- a. What challenges did you face ensuring that the intended user was the sole creator of the data?
  - b. Looking back on it, what would you have done differently, if anything?
  - c. What suggestions do you have for other investigators/research sponsors?
10. **[Device failure]** What steps did you take either prior to or during the study to manage issues related to device failure? **[Probe: tiered technical support for participants, study vs manufacturer provided]**
- a. About how frequently did devices fail during your study?
    - i. How did they fail?
  - b. Were there any safety concerns related to device failures that you had to be aware of?
    - i. **[If yes]** What steps did you take either prior to or during the study to manage these issues?
  - c. Looking back on it, what would you have done differently?
  - d. What suggestions do you have for other investigators/research sponsors?
11. **[Data integrity]** What steps did you take to ensure that data were not modified or corrupted in an undetectable way from the time it was collected by the device to the time the data were outputted from the device to data storage?
- a. What procedures did you put in place to ensure a detailed audit trail of any modifications made to study data? (Probe about what was tracked, how, at what level, when)
  - b. What challenges did you face, if any?
  - c. Looking back on it, what would you have done differently?
  - d. What suggestions do you have for other investigators/research sponsors?
12. **[Data security]** What steps did you take to ensure data security during storage?
- a. What about when transmitting data to the sponsor?

**Follow up as needed:**

- b. At what level (device vs storage-level) did data encryption occur?
  - i. Why did you choose that level?
- c. How were data transferred to the sponsor?
- d. What challenges did you face ensuring that data was stored securely? **[Probe about data platform/OS becoming obsolete; HIPPA compliance]**

- i. What about when transferring the data to the sponsor?
    - e. Looking back on it, what would you have done differently?
    - f. What suggestions do you have for other investigators/research sponsors?
13. **[Device reuse]** Were the devices that you used in your study ever reused by other participants -- or were the devices reused from an earlier study?
- a. Why/Why not?
  - b. **[If reused]** What steps did you take to ensure that data from the device was removed prior to reuse?
    - i. What challenges did you face?
    - ii. Looking back on it, what would you have done differently?
    - iii. What suggestions do you have for other investigators/research sponsors?
14. **[Safety signals]** As you know, with mobile devices there is the potential to collect a lot more data on patients than through traditional clinic-based instruments. With the mass amount of data that a single patient can create using a mobile device, how did you discern what was important and what was not?
- a. What was of concern as a potential safety issue and what was not?
  - b. How were safety-signals handled in your study?
    - i. Who was responsible for identifying and reporting safety issues?
    - ii. When might a physician become involved?
    - iii. What concern did the team have, if any, related to liability or malpractice if safety issues were not properly identified?
  - c. Looking back on it, what would you have done differently?
  - d. What suggestions do you have for other investigators/research sponsors?

### Section E: Monitoring

15. **[Study monitoring]** How was routine study monitoring done?

**Follow up as needed:**

- a. How was it decided what was necessary to monitor and what was not?
  - b. What specifically was monitored at the site-level versus at a central-level?
    - i. How was this determined?
  - c. Who conducted the monitoring?
  - d. When was monitoring done (real-time vs scheduled intervals vs other)? Why?
  - e. When using mobile devices to collect data, what types of data are reasonable for sponsors to have access to?
  - f. How was this different, if at all, from monitoring of studies using traditional data collection instruments?
  - g. What challenges did you face?
  - h. Looking back on it, what would you have done differently?
  - i. What suggestions do you have for other investigators/research sponsors?
16. **[Outcome monitoring]** As you know, the use of mobile devices allows for greater access to real-time data. In your opinion, would it be acceptable for the external monitoring committee (i.e., the DSMB) to have access to study outcome data in real-time?
- a. [If yes] How would this be done?

- i. What extra controls would need to be put in place? (e.g., through the DSMB charter)
- b. What would be the benefits of this?
- c. What would be the challenges?

Thank you for sharing all this information – it is all very helpful. I’d now like us to discuss how you interpreted the source data from the mobile device, but before we move on, is there anything else that you’d like to share with me about any considerations you had to make while using a mobile device to collect data in a clinical study?

## SECTION F: Analysis

17. What was different, if anything, when writing a data management plan or statistical analysis plan for data collected via mobile devices versus traditional data collection instruments?

### Follow up questions as necessary:

- a. How did you deal with the large volume of data during data cleaning?
- b. How did you make sense of the source data during data analysis?
- c. How were meaningful data identified? What I mean by “meaningful data” is data that are of particular interest in the dataset either for auditing purposes or for answering the research objectives.
- d. How did you determine what would be considered valuable missing data?
  - i. What were the reasons for missing data? **[Probe about patient confusion on how to use the device]**
- e. How were errors or missing data addressed?
  - i. How were any modifications to the data set during data preparation documented for auditing purposes?
- f. In the end, what types of data were actually used? What were discarded?
- g. Looking back on it, what would you have done differently?
- h. What suggestions do you have for other investigators/research sponsors?
  - i. What thoughts do you have on sponsors or manufacturers sharing their interpretation of the source data for others who want to use the device in the future?
  - ii. Should this information be widely available if used in clinical trials?

## SECTION G: Reporting

Finally, for our last topic, I’d like to know how you feel about real-time reporting – or feedback – of study data to participants.

18. In your study, did you allow for participants to receive real-time feedback of their study-related data?
- a. Why/Why not?
  - b. **[If yes]** What type of data was provided?
    - i. In what form? **[Probe: individual vs aggregate]**
    - ii. When were participants provided with this feedback?
    - iii. Were there any unanticipated consequences of providing data feedback to participants?
  - c. What scientific concerns did you have then – or do you now – about the impact of providing participants with data feedback on the integrity of the study?
  - d. Overall, what are the pros and cons of providing feedback to participants?

- i. Let's start with the pros.
- ii. Now the cons.

## **SECTION H: Closing**

In closing, I'd like to get your general recommendations for future investigators/research sponsors that may be interested in using mobile devices to collect objective data in their clinical drug trials.

19. What questions should other investigators/sponsors ask mobile device manufacturers when considering using mobile devices in clinical research?
20. What are your top three recommendations or areas of advice for other investigators/research sponsors when considering using mobile devices to collect data in clinical research?

That's the end of the questions that I have for you today. Do you have any final thoughts or questions that you'd like to ask about this study?

I want to sincerely thank you for your time and for the helpful information that you provided.

Thank you very much and I hope that you have a great day!