

Appendix B: Research Sponsor Interview Guide

SPONSOR INTERVIEW GUIDE
Value Assessment of Patient Group Engagement Methods
 INTERVIEW GUIDE – VERSION 1.0

1. Interviewer Name	
2. Participant ID#	
3. Interview Date (dd/mm/yyyy)	_ _ _ / _ _ _ / _ _ _ _ _
4. Participant agrees for interview to be recorded	Computer screen <input type="checkbox"/> Audio..... <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 the participant.
- Step 4:** Ask permission to record interview (audio and the computer screen showing the pile sort); tick the appropriate boxes in Q4 above.
- Step 5:** Turn on appropriate recorders 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:** 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 8:** Ask if the participant is interested in being re-contacted about the next phase of the research, which can be to pre-test a patient group engagement tool via another interview or to participate in a survey to identify the benefits and investments of the patient group engagement 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?
- In 2015, the Clinical Trials Transformation Initiative – referred to as CTTI – released recommendations on the effective engagement with patient groups around clinical trials. We are

interested in hearing your thoughts on the methods of patient group engagement that were identified in the recommendations.

- We'll also ask your opinion on the benefits that research sponsors gain from their engagement with patient groups and what you think are the investments or costs of engaging patient groups in medical product development.
- We'll use a moderated web-based activity today to hear your thoughts.
- There are no right or wrong answers to the questions I will ask, only opinions. 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 record the web-based interview – both the computer screen and audio – because I want to make sure I don't miss any of your comments. If you don't want your computer screen of the pile sort activity or your voice recorded, I will take detailed notes during the interview instead. Or I can audio-record the interview and not the computer screen. You may also want to turn off any email pop up messages so they are not recorded.
- The interview will take roughly 1 to 1 ½ hours. 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 interview.]

[If no, proceed with the interview.]

Is it okay if I turn on the recorder(s) now?

[If yes, begin recording now.]

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

Ok, let's get started!

SECTION B: Background information

1. Broadly speaking, what are the main types of activities that you do in medical product development?
2. What patient group engagement activities have you been involved with related to medical product development?
 - a. Beyond those activities, what patient groups activities has your company implemented related to medical product development?
3. What did your company invest in order to engage in these activities? (e.g., staff time, financial support)
4. What benefits do you believe your company has gained or will gain from engaging in these activities?
 - a. **[Probe, if needed]**
 - i. To your knowledge, has your company benefited in terms of total project revenue or net value of a project as a result of engaging with patient groups? Why/How?
 - ii. What intangible benefits do you believe your company has gained or will gain from engaging with patient groups in medical product development?

SECTION C: Pile sorting – Benefits to their patient group constituency

Now, I'd like to focus our discussion around CTTI's specific recommendations for patient group engagement. CTTI has identified 31 activities that patient groups can do in medical product development. We're trying to determine how research sponsors define "beneficial" when thinking about these patient group engagement methods. Thus, I'd like to hear your opinion regarding how beneficial each of these 31 patient group engagement activities are to your organization and reasons why.

[Instruct the participant to click the forward arrow button at the bottom of the screen]

On the screen in front of you, you should see the list of patient group engagement methods identified by CTTI. Please ask for clarification of any of the methods if needed.

I'd like you to sort these methods based on how beneficial you think each method is to your company. You'll notice that each method has been written on individual cards. We'd like you to sort – drag and drop using your cursor – each method into one of four piles. The four piles are:

- a) Patient group engagement methods that you feel will provide a **high benefit** to your company
- b) Patient group engagement methods that you feel will provide a **moderate benefit** to your company
- c) Patient group engagement methods that you feel will provide a **low benefit** to your company
- d) Patient group engagement methods that you feel will provide **no benefit** to your company

The methods do not need to be distributed across each category. There may be empty piles. I'll give you a few minutes to review the methods and their descriptions before we move on to the pile sorting activities.

Let us now talk about each pile you created. Let's start with the "high" pile.

High benefit

5. Among the patient group engagement methods placed in the "high" pile, what are the common threads among them that lead to a "high" benefit?
6. What are the key differentiating factors you considered when placing these methods into the "high" benefit pile instead of one of the other piles?
 - a. **[Probe, if needed]** What type of benefits do you see coming from the methods that you have placed in the "high" benefit pile?

Moderate benefit

7. Among the patient group engagement methods placed in the "moderate" pile, what are the common threads among them that lead to a "moderate" benefit?
8. What are the key differentiating factors you considered when placing these methods into the "moderate" benefit pile instead of one of the other piles?
 - a. **[Probe, if needed]** What type of benefits do you see coming from the methods that you have placed in the "moderate" benefit pile?

Low benefit

9. Among the patient group engagement methods placed in the "low" pile, what are the common threads among them that lead to a "low" benefit?
10. What are the key differentiating factors you considered when placing these methods into the "low" benefit pile instead of one of the other piles?
 - a. **[Probe, if needed]** What type of benefits do you see coming from the methods that you have placed in the "low" benefit pile?

No benefit

11. For the "no benefit" pile, for what reasons did you feel these patient group engagement methods would not lead to any benefit?

SECTION D: Pile sorting – Investments by the patient group

Next, we'd like you to sort these same methods one more time. This time, please sort the methods into one of four piles based on the degree of investment required to conduct the method. That is, whether the method requires a (1) high, (2) moderate, (3) low, and (4) no investment to implement as described. As with the last exercise, the methods do not need to be distributed across each category. There may be empty piles. Also, note that we provided a fifth pile called "unsure" or "not applicable" if you are unsure of the investments required to complete a particular patient group engagement method or if the method isn't relevant to your work. ***[Note to the interviewer – do not define "investment" for the participant, rather allow them to self-describe what they feel is an investment.]***

Let us now talk about each pile you created. Let's start with the "high" pile.

High investment

12. Among the patient group engagement methods placed in the "high" pile, what are the common threads among them that lead to a "high" investment?
13. What are the key differentiating factors you considered when placing these methods into the "high" investment pile instead of one of the other piles?
 - a. ***[Probe, if needed]*** What types of investments are generally needed for the methods you placed in the "high" investment category?

Moderate investment

14. Among the patient group engagement methods placed in the "moderate" pile, what are the common threads among them that lead to a "moderate" investment?
15. What are the key differentiating factors you considered when placing these methods into the "moderate" investment pile instead of one of the other piles?
 - a. ***[Probe, if needed]*** What types of investments are generally needed for the methods you placed in the "moderate" investment category?

Low investment

16. Among the patient group engagement methods placed in the "low" pile, what are the common threads among them that lead to a "low" investment?
17. What are the key differentiating factors you considered when placing these methods into the "low" investment pile instead of one of the other piles?
 - a. ***[Probe, if needed]*** What types of investments are generally needed for the methods you have placed in the "low" investment pile?

No investment

18. For the "no investment" pile, for what reasons did you feel these patient group engagement methods would not need any investment?

Section E: Weighing benefit versus investment

19. **[Ask if any of the impacts listed below where not previously discussed]** Now let us talk about other potential impacts of patient group engagement.
- How might engaging with patient groups impact the probability that a company will choose to advance drug development after a study is completed?
 - Assuming the company proceeds with drug development, how might engaging with patient groups impact the **timing** of getting the drug on the market?
 - How might engaging with patient groups impact the probability that regulatory authorities will approve the drug?
 - How might engaging with patient groups effect whether or not a clinical trial or regulatory review is completed in the time planned?
 - How might engaging with patient groups impact how actual revenue compares to predicted revenue?
20. In your opinion, are there some benefits of patient group engagement so great that they are worth any investment?
- [If yes]** What kinds of benefits?
 - Why?
21. Conversely, are there any investments that are so large that they outweigh the benefits?
- [If yes]** What kinds of investments?
 - Why?
22. How useful do you feel it is to talk about patient group engagement methods using terms such as benefits versus investments like we did today?
- [If benefits and investments are not useful]** In your opinion, what might be other ways of determining the value of patient group engagement methods in medical product development?

SECTION F: Activity relevance to patient group

23. Our last questions focus on CTTI's description of the patient group methods. Are there any descriptions that could be made clearer, more defined, or more relevant to your organization?
- [If yes]** Which ones?
 - What could be said to make them clearer/more defined/more relevant?
24. Are there any patient group engagement methods that you felt were missing from our list?
- [If yes]** Which ones?
 - What could be said to describe that activity?

SECTION G: Closing

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 or CTTI's recommendations on patient group engagement?

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

If you'd like for us to re-contact you with a summary of the results from our interviews please click the link on the screen and fill in your contact information. Your name and contact information will not be linked to your responses during the interview. Please click the box at the bottom of this screen if you are interested in participating in phase 2 of this research. This would involve either pre-testing the survey or taking the survey that results from the data we have collected during this phase. If you'd prefer that we do not re-contact you, then go ahead and click the forward arrow button at the bottom of the screen and that will submit your pile sorting results and end our interview.

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