

# PCTTI- PATIENT GROUPS AND CLINICAL TRIALS INTERVIEW GUIDE

Questions for Industry, Academia , NIH, FDA

## Introduction

- Welcome and thank them for participation
- Introduce ourselves and reflect the intent to keep the interview to one hour.
- Describe CTTI and purpose of project
- Describe purpose of this interview: to explore in-depth the topic of engagement between patient groups and research sponsors/investigators around clinical trials. Through our interviews, we are trying to gain a better understanding of your experiences with previous engagement efforts with patient groups. We are particularly interested in hearing about what you thought went well in the engagement process as well as what the obstacles you have found got in the way of a successful engagement. We will also be discussing what you see as the elements of success and what you see as the potential pitfalls for patient advocacy within the research design and operations of clinical trials.
- There are no right or wrong answers – only opinions so please feel free to share your thoughts and ideas.
- All your ideas are important to us, and we will be audio recording this interview so we make sure we don't miss anything you have to say for the purposes of our summary report when all the interviews are complete.
- I want to assure you, however, that all the information collected will be confidential and none of your comments will be associated with your name or your company. All interviews will be de-identified and there will be no reference to specific people or companies in the report. Each respondent will be identified only by his or her respective category (representative from a patient group, academia, industry, etc.)
- *You are not required to answer all of the questions; you may pass on any question you do not wish to answer.*
- *Your participation is voluntary. You can stop the interview and your participation at any time.*
- ***\*Do you consent to participate in this interview about the Engagement of Patient Groups in the Clinical Trial process?***

## Warm-up

1. I'd like to begin by having you tell me a little about yourself and your role at your organization.
2. When you hear the words "patient engagement," what immediately comes to mind? (top-of-mind associations)

## Questions for Industry/Academia/NIH/FDA

- 3 How do you define (How would you describe?) patient group engagement at your organization? Who usually initiates a process of patient engagement?
- Can you give me examples of how your organization has engaged patient groups specifically around clinical trial development or operations?
  - In general, what does your organization typically give and what does your organization typically get from patient engagement efforts?
  - Ideally, what do you seek from the patient group in terms of the engagement(e.g.. funding, help with recruiting, input on study design)?
4. What do you see as the value of patient group engagement? Ideally, what kinds of impact would mean success in terms of patient group engagement in clinical trials?
5. Is there a specific process at your organization for engaging with patient groups?
- If so: please describe.
  - If not, do you think that having a process would help others in learning about engagements?
  - Are there particular characteristics you look for in patient groups such as area of focus, reach, tools such as registries or biobanks, or ability to provide funding?
6. What, if any, structural or individual support is there at your organization for patient group engagement?
- Do you actively seek their support to engage with patient groups?
  - Is accessing this internal resource part of your patient engagement process?
7. In general, how well have the engagements met your planned expectations for engaging the patient group? Why do you say that?
8. What has been successful about previous engagements?
9. What have been the biggest challenges/frustrations about previous engagements?
10. In your experiences, what, if any, barriers did you have to remove or what problems did you have to resolve in order to have a successful engagement? How did you overcome those barriers?

11. Think back to one patient group engagement experience that you found particularly successful. What do you think made that experience successful? Were there obstacles you had to overcome to achieve your goals.

12. If you were advising others on best practices for patient group engagement, what would you recommend? (open-ended first) then probe:

- a. Processes/ Methods for achieving success?
- b. Pitfalls to avoid to reduce failures?

13. What if any differences do you think that patient engagements have made at your organization? (OR What if any impacts do you think that patient engagements have had at your organization?)

- a. If none: What could you recommend to change that in the future?
- b. If so: Can you tell me more about that?
- c. What is the difference that the engagement resulted in?

14. Do you validate or measure value of partnerships with patient groups around clinical trials at your organization? If so, in what way? What have you found?

- a. What are the metrics?
- b. How would you explain the “business case” or “value case” of engaging with patient groups around clinical trials to decision makers in your company?
- c. . Has your organization ever structured a business deal with patient groups that involved royalties or paybacks in therapy development? If so, what did you get from the patient groups upfront?

15. If you could wave a wand how would you change the process of patient engagement at your organization to make it different or better as far as you are concerned?

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Questions for Patients Groups

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- Describe CTTI and purpose of project
- Describe purpose of this interview: to explore in-depth the topic of engagement between patient groups and research sponsors/investigators. Through our interviews, we are trying to gain a better understanding of your experiences with previous engagement efforts with industry or academic researchers. We are particularly interested in hearing about what got in the way of a successful engagement.
- We will also be discussing what you see as the most important elements of success and what you see as the potential pitfalls for patient advocacy within the research design and operations of clinical trials.
- There are no right or wrong answers – only opinions so please feel free to share your thoughts and ideas.
- All your ideas are important to us, and we will be audio recording this interview so we make sure we don't miss anything you have to say for the purposes of our summary report when all the interviews are complete.
- I want to assure you, however, that all the information collected will be confidential and none of your comments will be associated with your name. All interviews will be de-identified and there will be no reference to specific people in the report. Each respondent will be identified only by his or her respective category (representative from a patient group, academia, industry, etc.)
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**Warm-up**

1. Can you tell me your name and a little about yourself and the patient group you work with?
  
2. How did you first come to work with this patient group?

3. When I say “clinical trials based patient group engagement” what immediately comes to mind?

### **Questions for Patient Groups**

4. How do you define (How would you describe?) clinical trials based patient group engagement with Sponsors (Industry or Academia) at your organization?
  - a. Can you give examples of how you have worked with Sponsors specifically?
5. Is there a specific process for engaging with Sponsors?
  - a. If yes, please describe
  - b. If not, do you think a process would help others (who? Others in their organization?) in learning about engagement? How?
6. What kinds of expectations do you have when you are about to be involved in a patient group engagement experience?
  - a. Have you ever executed a contract with a sponsor or investigator around a clinical trial? If so , what were the key elements?
  - b. . Has your organization ever structured a deal that involved royalties or paybacks in therapy development?
7. In general, how well have the engagements you have been involved in met your expectations? (Have them elaborate). (If they met their expectations, ask: In what way did they meet your expectations? If not: Why did they not meet your expectations?) How well did they meet your expectations in terms of involvement with Sponsors?
8. What has been successful about previous engagements?
9. What have been the greatest challenges or frustrations about previous engagements?
10. Think for a moment about an engagement experience that you found particularly successful. Can you tell me about it?
  - a. What made it successful?
  - b. What did you like most about it?
  - c. What was the impact of it?
  - d. Were there any barriers that you had to remove or resolve in order to be successful in that engagement?

- e. If so, what were they and how did you overcome them?
11. If you were advising other patient groups on best practices for working with Sponsors, what would you recommend? (open-ended first)
    - a. What would you recommended as Processes/Methods for achieving success?
    - b. Pitfalls to avoid to reduce failures?
    - c. Can you list potential areas to engage with sponsors?
  12. Is there a difference in these recommendations or how you work specifically with Industry vs. Academic Sponsors?
  13. What structural or individual support is there at your organization for engaging with Sponsors?
  14. If you could create the ideal situation for patient group engagement in clinical trials, tell me what it would be like. Now tell me what it wouldn't be like.
  15. Do you have any other comments that we didn't touch upon in our conversation but that you think is important for me to know?

Thank you so much for taking the time to share your thoughts and ideas with me today. They were be extremely valuable for providing sponsors and patient groups with elements to make these collaborations more successful.