

# Appendix II: Patient Listening Sessions

## Interview Guide

### PRA Statement

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### Introduction (3-5 min)

*Introduction and context:* I'm part of the team supporting PAS on their current patient engagement strategy.

Thank you for agreeing to participate in this interview. For context, are you aware of the work we are doing with the PAS team? [We are trying to understand what aspects of the current Listening Session design work well and where there may be opportunities for improvement in order to maximize the usefulness of Listening Sessions to both FDA staff and patients, caregivers, or their advocates. We are also examining the *For Patients* section of FDA.gov website to ensure that it is closely aligned with the needs of patients and their advocates.]

*Objectives for this interview:* We will focus the majority of our discussion on the Listening Sessions, both internally and externally triggered Listening Sessions. The conversation will be an open discussion. We will cover the following topics:

- + Your background and role
- + The process of participating in a Listening Session
- + The Listening Session in detail
- + How you otherwise share information related to the condition
- + A series of questions that we'll ask you to rate 1-5
- + Other questions related to how patients may access information on the FDA website

We hope to understand what you are considering and experiencing when engaged with the Listening Sessions, what you expected to take away from them, and how they influenced your thinking and actions.

*Process and confidentiality:* We are very interested in your personal opinion. Please be as open and honest as possible, as your feedback will be essential to understanding how you engage with the Listening

Session in your role. Your input will remain anonymous and will be presented in a summary / aggregate form. We will record your name, role, and affiliation only to include it in individuals who contributed to the output of our recommendations to PAS. However, names, roles, affiliations, or any other personally identifiable information will not appear in any publicly-available outputs of the project.

We have 60 minutes in total. Sometimes, I will ask you to explain more about what you say. That may seem simple but your answers help me understand your point-of-view. If at any point you don't understand anything please stop me and I can clarify what I mean. And if there's any question you don't feel comfortable answering, please just let me know.

## Section 0. Background

- Can you briefly introduce yourself to me and share who you are?

*For Advocacy Groups*

- Could you tell me a bit about your role? How long have you been with [your organization]?
- What are your day-to-day responsibilities?
- What motivated you to work for [your organization]?

*For Patients*

- Could you tell me a little bit about your experience with your condition?
- How long ago were you diagnosed?
- What has the experience been like so far for you?
- What advice would you give to someone who has been recently diagnosed?

## Section 1. Listening Session Journey

*We'd like to start with understanding the end-to-end experience of Listening Sessions*

- If you were going to describe Listening Sessions in one word, what word would you use?
- Were you part of a session that you requested, or, one that your presence was requested?
  - *For a session that you requested, how did you feel about the process?*
    - Was it clear how to request a session?
    - What was the easiest part?
    - What was the most difficult part?
    - What do you wish you had known?
    - What sections of the process do you think could be improved?
    - Did you receive any materials or information after the session?
      - How helpful was that information?
  - *For a session that your presence was requested, how did you feel about the process?*
    - Who reached out to you? What did they tell you?
    - How easy was it to participate?
    - What was difficult?
    - How prepared did you feel to attend?
    - What do you wish you had known?
    - What sections of the process do you think could be improved?
    - Did you receive any materials or information after the session?
      - How helpful was that information?
- If you were going to revamp the process for setting up a Listening Session, what sections would you leave as is? What improvements would you make to the process?

## Section 2. Listening Session in Detail

*Now, we'd like to know in more detail about your experience with Listening Sessions themselves*

- What was your experience in performing a Listening Session?
  - What was positive?

- o What could be improved?
- What did you hope to get out of the Listening Session?
- How well were your expectations of the Listening Session met?
- *Have you attended a Listening Session where your presence was requested?*
  - o What was that experience like?
  - o What were your favorite parts of being involved in the session?
  - o What were your least favorite parts?
  - o What kinds of questions were you asked?
  - o What did you wish they had asked you?
  - o What do you think could be improved?
- *Have you attended a Listening Session requested by your group?*
  - o What was that experience like?
  - o What were your favorite parts of being involved in the session?
  - o What were your least favorite parts?
  - o What kinds of questions were you asked?
  - o What did you wish they had asked you?
  - o What do you think could be improved?
- If you were going to run a Listening Session yourself, what would you keep from the experience?
  - o What would you remove?
- What do you think makes for a successful Listening Session?
- What are your aspirations for the Listening Sessions?

### **Section 3: Patient Engagement Related Questions**

*We have a couple questions we'd like to ask you about engaging with stakeholders related to your disease state*

- What are the other ways you try to share information around this condition?
- Who else do you wish you could engage to talk about your condition?
- Did the Listening Sessions feel fruitful for you? Why or why not?
- Have you participated in other Listening Session-like events?
  - o How did these sessions compare?
  - o What did you like about those other sessions?
  - o What didn't you like?

### **Section 4: Metric Measurement**

*We'd like to ask you a series of questions and get a number answer to understand how you rate your experience with Listening Sessions*

1. How valuable did you find the Listening Session to be on a scale of 1 to 5? 1 being not valuable at all, 5 being incredibly valuable.
2. How willing would you be to attend another Listening Session on a scale of 1 to 5? 1 being not willing at all, 5 being extremely excited to attend again.
3. What is the likelihood you would recommend someone request or perform a Listening Session in the future on a scale of 1 to 5? 1 being would not recommend, 5 would be highly recommend
4. How inspirational did you find the Listening Session to be? 1 being not inspirational at all, 5 being extremely inspirational
5. How useful was the outcome of the Listening Session for you? 1 being not useful at all, 5 being extremely useful

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### **Section 5: Other Questions**

*We have a couple questions we'd like to ask you about the FDA website as it relates to patients and their advocates as users*

- Have you ever seen the FDA “*For Patients*” section of the website?
  - What are your thoughts?
  - What works?
  - What doesn’t?
- What should be the objective of a patient-centric section of the FDA website?
- How could the FDA benefit from a patient-centric section of the FDA website?
- How could patients and their advocates benefit from one?
- How else could the FDA enhance the opportunity to engage with patients through its website?

### **Section 6: Closing**

Again, thank you for taking the time to share your experience with us. It’s very important for us to hear from you directly about what you need from a Listening Session.

Before we close, we’d love to hear from you about anything that you wish you could tell us that we didn’t ask about that could better contribute towards that goal.

From what you shared, we’re going to start to think about solutions, and, it’s possible that we’d want to revisit you to share them with you to get your feedback and insights. Is that something you would be interested in?