

Appendix I: *For Patients* Website Interview Guide

PRA Statement

OMB Control No. 0910-0697

Expiration Date: 12/31/2020

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control for this information collection is 0910-0697 and the expiration date is 12/31/2020. The time required to complete this information collection is estimated to average 105 minutes per response, including the time for reviewing instructions and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestion for reducing burden to PRASStaff@fda.hhs.gov.

Your participation/nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-responders), this information collection fully complies with all aspects of the Privacy Act and data will be kept secure to the fullest extent allowed by law.

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 examining the *For Patients* section of FDA.gov website to understand how the FDA could best address the needs of patients, caretakers, or their advocates through a patient-centric website.]

Objectives for this interview: We will focus the majority of our discussion on how you seek information and provide input on the medical condition relevant to you and any products you use for its management or treatment. The conversation will be an open discussion. We will cover the following topics:

- + Background and context – about you and your family, how you learned about the condition, experience with it
- + Looking for treatment options – how you research medical information related to the condition
- + Looking for product information – how you look for more information on products that you have been prescribed
- + Sharing feedback on products – whether and how you provide feedback about your treatments
- + Looking for information on alternate treatments – whether you have considered clinical trials or sought information related to expanded access
- + Engaging with the FDA, HHS in general, or any other government agency – whether and how you have engaged with the FDA or any other government agency
- + Evaluation of FDA.gov – an experiential component aiming to understand your experience navigating a section of the FDA website

You need not have turned to the FDA to meet any of these needs (i.e., you might have never looked at the FDA's website before, and that's ok). We will focus the discussion depending on how many of the above apply—I know not all necessarily will. At the tail end of the visit, I will ask you to visit the FDA website and talk me through your expectations / thoughts / feelings as you navigate the site—the experiential component.

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 information found on the Internet and government websites like FDA.com for information and to provide input. 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 90 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 and context

- Tell us a little bit about yourself. Where are you from and what do you do?
- How long have you been doing that?
- How old are you?
- [If we don't know already from the recruiting] What medical condition do you think about the most?
- When do you normally think about it?
- What prompts you to think about [this condition]?
- When were you/your [relationship] diagnosed with [this medical condition]?
- What were your first thoughts after learning about the diagnosis?
- How did you find out more about [this medical condition]?

Section 1. Looking for treatment options

- How did you research treatment options?
 - What online resources did you use?
 - Who did you talk to?

- How much time did you spend looking into all the options?
- How easy was it to find out information about all your options?
- How informed did you feel when making the choice?
- How did this research fit in with everything else that was going on in your life?
- What was your state of mind when trying to figure out what your treatment options were?
- What was the hardest part about picking a course of treatment?
- How did you make the decision?
- What advice would you give someone going through the same thing?

Section 2. Looking for product information

- Were you prescribed a product or device for [this medical condition]?
 - If no, skip section
- Had you heard of this product before?
- What was your reaction to having [this product] prescribed?
- Were you looking to find more about this product?
 - If no, skip to next
- What prompted you to look for more information about it?
- How did you go about finding more information?
 - What online resources did you use?
 - Who did you talk to?
- How easy was it to find more information about the product?
- How long did you spend researching the product?
- How informed did you feel after your research?
- What was the hardest part of finding the information you were looking for?
- What was your state of mind during the process?

- How did you decide to take/use [this product]?
- What advice would you give someone going through the same thing?

Section 3: Sharing feedback on products

- Have you ever tried to provide feedback on a medical product (drug or device)?
 - If no, skip section
- Where did you provide feedback?
- What prompted you to do so?
- How did you go about providing feedback?
- How easy was it to provide feedback about the product?
- How long did you spend on it?
- What was the hardest part of providing feedback?
- What was your state of mind during the process?
- What advice would you give someone also trying to share input?

Section 4: Looking for information on alternate treatments

- Have you ever considered doing a clinical trial or getting involved in expanded access treatment?
 - If no, skip section
- What prompted you to do so?
- How did you research expanded access options/clinical trials going on?
 - What online resources did you use?
 - Who did you talk to?
- How much time did you spend looking into the options?
- How easy was it to find out information about all your options?
- What was the hardest part about researching the options?

- How did this research fit in with everything else that was going on in your life?
- What was your state of mind when trying to decide whether or not this would be right for you?
- How did you make the decision to do it/not do it?
- How informed did you feel when you were making the decision?
- What advice would you give someone going through the same thing?

Section 5: Engaging with the FDA, HHS in general, or any other government agency

- Have you ever gotten involved with government-related patient engagement activities?
 - If no, skip section
- How did you get involved?
- What prompted you to do so?
- How did you go about researching how you could get involved?
- How easy was it to get involved?
- How long did you spend researching before you first [went to meeting/listening session/other]?
- What was the hardest part of getting involved?
- What was your state of mind during the initiative?
- What advice would you give someone also trying get involved as a [patient representative/other]?

Section 6: Evaluation of FDA.gov

Now we're going to switch over to looking at a website so that we can ask you a few questions about it. Please open your browser and when you're ready, please visit *FDA.gov/ForPatients*.

General understanding of FDA and interest in *For Patients* site

- (If not covered during the first section) Are you familiar with the FDA?
 - If yes: Can you tell me a little bit about what you know?
- Have you ever visited this website before?
- Take a minute to scan this first page of the site, and when you're ready, please describe to us what you think it's about or what it offers.
- What are your general thoughts on the look and feel of the site?
- Do you think this site would be useful to you?

Home screen: initial reactions

- What appears to be the most important information on this screen?
- Is there anything you don't understand on this screen, or that seems unclear?
- Is there anything on this screen you expect to see that isn't already here?
- What information would you be most interested in exploring on this site? (Instruct user to click link)

Second level (any page)

- Take a minute to scan this page. When you're ready, let me know what were you expecting to find when visiting this page?
- Is there anything you don't understand on this screen, or that seems unclear?
- How would you interact with this page?
- What would you be interested in doing next?
- Let's stay on this page for a second--how would you return to the main page that we were looking at before?

Free browse

- Now for a few minutes, I'd like you to freely browse the site. As you explore, talk us through any thoughts you have about what you're seeing and reading—for example, things that seem unclear, difficult or confusing, as well as things that are interesting to you.

Rating

For this next set of questions, I'd like you to respond on a scale of 1-5, 1 being lowest and 5 being highest.

- How easy was it to find your way around the site?
- How easy was it to find content you were looking for?
- How easy was it to understand the content of the site?
- How useful was the content to you?
- How trustworthy or credible was the content to you?
- Please rate your overall experience with the site.

Final thoughts

- As you were exploring the site, how did you feel?
- What improvements would you like to see?
- What is the likelihood you would visit this site again?
- Is there anything else you'd like to give feedback on that we didn't ask you about?

Closing

Thank you for taking the time to share your experience with us. It's very important for us to hear from you directly and the information you shared has been extremely valuable.