

Appendix I: *For Patients Website* Interview Guide

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INTRODUCTION

Hi, *name of participant*. My name is _____ and I'm with FDA's Office of Patient Affairs. I'm going to be walking you through this session today.

Before we begin, I have some information for you, and I'm going to read it to make sure that I cover everything. We're asking patients, caregivers and advocates to use our draft website and give us your feedback. The session should take approximately 60 minutes.

First, I want to share that we're testing the website, not you. You can't do anything wrong here. We want to know your thoughts and opinions on everything. Also, please don't worry that you're going to hurt our feelings. We're doing this to improve the website, so we need to hear your honest reactions.

As you use the website, I'm going to ask you as much as possible to try to think out loud: to say what you're looking at, what you're trying to do, and what you're thinking. This will be a big help to us. When we are done getting feedback from all website testers, we will combine all the feedback into a recommendations report. Your name will not be used in connection with your thoughts and feedback. Based on your feedback and all the other participants, the Office of Patient Affairs will make changes to create a website that is more "patient friendly." We will notify you by email when the new website is live.

If you have any questions as we go along, just ask them. I may not be able to answer them right away, since we're interested in how people do when they don't have someone sitting next to them to help. But if you still have any questions when we're done, I'll try to answer them then. And if you need to take a break at any point, just let me know.

With your permission, we're going to record what happens on the screen and our conversation. The recording will only be used to help us figure out how to improve the site, and it won't be seen by anyone

except the people working on this project. Once we review everything and the project is finished, we will destroy the recording.

Now that you know more about the project and what you will do, would you mind reviewing and signing a permission form? It says that we have your permission to record you, and that the recording will only be seen by the people working on the project.

Thank you for signing our permission form in advance and allowing us to record this session. *(If any observers)* Also, there are a few people from the Web design team observing this session online. *Insert first name(s) of observer(s)* are observing today.

Do you have any questions so far?

If you were to tell you that FDA has developed a site for patients, what type of information would you expect to see? What type of actions would you expect to be able to take on this site? *(e.g., request information, post a comment, sign up for meetings, etc.)* What tasks might you be able to complete on the site?

We often use the term “patient engagement”. What does that term mean to you? Is there a better term we can use to capture the idea of having patient involvement and input in the regulatory process?

OK, great. We will begin now.

WEBSITE REVIEW

*Click on the bookmark for the **For Patients** webpage. Give participant approximately 5 minutes to complete first impressions of webpage.*

General Task: First Impressions--For Patients Website

Just look around the website and share your initial thoughts with me out loud. For example:

- First, I'm going to ask you to look at this page and tell me what would you click on first? *(30 seconds max.)*
- OK. Now let's look around the page a little more. You can scroll if you want to, but don't click on anything yet. Briefly, what do you think the purpose of this site is? *(30 seconds max.)*
- What interests you the most? Why?
- What might you be able to find on this website?
- Why would someone come to this website?
- Do you see someone like you using this website? Why? Why not? Who also might use this website?
- What do you think of the overall look and feel of the website? What do you like/what could be improved?

Below are some additional questions/prompts (if necessary).

- Can you identify with the images and visuals on the page? Why or why not? Do the visual elements help reinforce the information presented? Why or Why not?
- How does the organization of the (content, layout?) seem to you? Does the website seem well organized at first glance? If not, what might help with organization or layout of the website?
- Does any information appear to be missing? Anything else you think should be added?

TARGETED TASKS

Thanks. Now I'm going to ask you to try doing some specific tasks using this website. I'm also going to ask you to do these tasks without using Search. We'll learn a lot more about how well the site works that way. And again, as much as possible, it will help us if you can try to think out loud as you go along.

Starting from the For Patients page of the FDA website, ask participants to complete the following tasks.

Targeted Task: Device Approvals

You are a patient and you heard about a device that was approved in Canada. You are wondering about how the approval process works in the US. Show me how and where you would find that information on the website.

Answer:

<https://www.fda.gov/patients/learn-about-drug-and-device-approvals>

Targeted Task: Expanded Access

You heard about a drug for your disease or condition that is being developed and tested in the U.S. The drug has not been approved yet by the FDA for patient use. You think there might be a way to get to use that drug. You want to learn more about it and the process for accessing the drug. Show me how and where you would find that information on the website.

Possible Answers:

<https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options>

- <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>
- <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-investigational-drugs>
- <https://www.fda.gov/news-events/public-health-focus/expanded-access>
(Non-PAS/external link)
- <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try>

Targeted Task: Clinical Trials

You want to find if there is a clinical trial for your disease or condition, show me how and where you would find that information on the website.

Answer:

<https://www.fda.gov/patients/clinical-trials-what-patients-need-know>

Targeted Task: Patient Engagement

You have heard that there are ways for patients and advocates to engage with FDA. Show me how and where on the website you would find more information and possible opportunities for patient engagement.

Possible Answers:

<https://www.fda.gov/patients/learn-about-fda-patient-engagement>

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/initiatives-patients-engage-fda>

Targeted Task: Reporting an Adverse Event to FDA

You are taking a medication and are having some unexpected side effects. As a result, you want the FDA to be made aware of a potential safety problem with the medication. Show me how and where would tell the FDA about this problem.

Answer:

<https://www.fda.gov/patients>

Choose Featured

<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=consumer.reporting1>

(Non-PAS/external link)

Targeted Task: Contacting FDA

You want to request a meeting with FDA. Besides calling the FDA, show me how and where you can contact the FDA on the website.

Answer:

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/patients-ask-fda>

Targeted Task: Listening Sessions

You have heard that FDA has something called “Patient Listening Sessions.” Please show me where you would find more information about them and how you might request one.

Answer:

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/patient-listening-sessions>

<https://www.fda.gov/patients/learn-about-fda-patient-engagement/patients-ask-fda>

WEBPAGE REVIEW

Learn About FDA Patient Engagement

*Click on the bookmark for the **Learn About Patient Engagement** webpage. Give participant approximately 5 minutes to complete first impressions of webpage.*

General Task: First Impressions — Learn About Patient Engagement

Just look around the website and share your initial thoughts with me out loud. For example:

- First, I’m going to ask you to look at this page and tell me what would you click on first? *(30 seconds max.)*
- OK. Now let’s look a little more around the page. You can scroll if you want to, but don’t click on anything yet. Briefly, what do you think the purpose of this site is? *(30 seconds max.)*
- What interests you the most? Why?
- What might you be able to find on this website?
- Why would someone come to this website?
- Do you see someone like you using this website? Why? Why not? Who also might use this website?
- What do you think of the overall look and feel of the website? What do you like/what could be improved?

Below are some additional questions/prompts (if necessary).

- Can you identify with the images and visuals on the page? Why or why not? Do the visual elements help reinforce the information presented? Why or Why not?

- How does the organization of the (content, layout?) seem to you? Does the website seem well organized at first glance? If not, what might help with organization or layout of the website?
- Does any information appear to be missing? Anything else you think should be added?

WEBPAGE REVIEW

FDA Patient Overview

*Click on the bookmark for the **FDA Patient Overview** webpage. Give participant approximately 5 minutes to complete first impressions of webpage.*

General Task: First Impressions — FDA Patient Overview

Just look around the website and share your initial thoughts with me out loud. For example:

- First, I'm going to ask you to look at this page and tell me what would you click on first? *(30 seconds max.)*
- OK. Now let's look a little more around the page. You can scroll if you want to, but don't click on anything yet. Briefly, what do you think the purpose of this site is? *(30 seconds max.)*
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WEBPAGE REVIEW

FDA Patient Engagement Partnerships

*Click on the bookmark for the **FDA Patient Engagement Partnerships** webpage. Give participant approximately 5 minutes to complete first impressions of webpage.*

General Task: First Impressions — FDA Patient Engagement Partnerships

Just look around the website and share your initial thoughts with me out loud. For example:

- First, I'm going to ask you to look at this page and tell me what would you click on first? *(30 seconds max.)*
- OK. Now let's look a little more around the page. You can scroll if you want to, but don't click on anything yet. Briefly, what do you think the purpose of this site is? *(30 seconds max.)*
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- Does any information appear to be missing? Anything else you think should be added?

WEBPAGE REVIEW

FDA Patient Engagement Opportunities

*Click on the bookmark for the **FDA Patient Engagement Opportunities** webpage. Give participant approximately 5 minutes to complete first impressions of webpage.*

General Task: First Impressions — FDA Patient Engagement Opportunities

Just look around the website and share your initial thoughts with me out loud. For example:

- First, I'm going to ask you to look at this page and tell me what would you click on first? *(30 seconds max.)*
- OK. Now let's look a little more around the page. You can scroll if you want to, but don't click on anything yet. Briefly, what do you think the purpose of this site is? *(30 seconds max.)*
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WEBPAGE REVIEW

FDA Resources for Patients

*Click on the bookmark for the **FDA Resources for Patients** webpage. Give participant approximately 5 minutes to complete first impressions of webpage.*

General Task: First Impressions — FDA Resources for Patients

Just look around the website and share your initial thoughts with me out loud. For example:

- First, I'm going to ask you to look at this page and tell me what would you click on first? *(30 seconds max.)*
- OK. Now let's look a little more around the page. You can scroll if you want to, but don't click on anything yet. Briefly, what do you think the purpose of this site is? *(30 seconds max.)*
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WRAP UP

Thank you, your insights today were very helpful. If you'll excuse me for a minute, I'm just going to see if the people on the team have any follow-up questions they'd like me to ask you.

Check to see if the observers have any additional questions. Ask the observers' questions, then probe anything you want to follow up on.

Do you have any final questions for me? Anything else you'd like to share with us regarding the website? We appreciate you helping us with this important project and providing your honest opinions. It's feedback like yours that helps FDA improve our website. Thanks again for your time today.