

United States Food and Drug Administration
Qualitative Feedback on FDA Service Delivery
OMB Control Number 0910-0697
Gen IC Request for Approval

Title of Gen IC: (OC) Assessments of Patient and Patient Advocate Experience with the FDA *For Patients* Website and FDA Patient Listening Session program

1. Statement of Need

The FDA Patient Affairs Staff (PAS) goal is to coordinate and support patient engagement activities across the medical product centers to facilitate awareness and collaboration with patient stakeholders (patients, caregivers, patient groups, and patient advocates). PAS is a group within the FDA that is actively seeking the input of individuals within and outside of the FDA on several projects developed to enhance the quality of formal and informal mechanisms by which the FDA engages with its end customers—our patients.

The *For Patients* website and FDA Patient Listening Session program are two projects through which PAS seeks to meet this goal, and ultimately, meet the needs of patients as best as possible.

The *For Patients* website is the primary channel by which patients can (i) explore what the FDA does; (ii) look for information on treatment options and products; and (iii) engage the FDA through various formal and informal mechanisms, including the FDA Patient Listening Sessions.

The FDA Patient Listening Session program provides an opportunity for patients, caregivers, and patient organizations to connect directly with the FDA about their health condition and help us understand what is most important including the physical and emotional burdens. The Patient Listening Sessions are intended to complement existing processes of getting patient input and engagement at the FDA, such as the FDA Patient Representative Program, Patient-Focused Drug Development (PFDD) program, and the CDRH Patient Engagement Advisory Committee (PEAC).

The desired impact is:

- **Strengthen FDA's outward facing** website *For Patients* to ensure it is discoverable, consumable, and actionable to best serve the Office of Clinical Policy and Programs patient audiences.
- Demonstrate the value of FDA Patient Listening Sessions and **enhance future FDA Patient Listening Sessions to be even more useful** to FDA review staff, patient communities (patients, caregivers, patient groups, advocates) going forward.
- **Further build and strengthen PAS' ability to support programs** related to patient engagement on cross-cutting topics for the FDA.

2. Intended Use of the Information

- **Define recommendations for the future state of the *For Patients* section of FDA.gov that more closely aligns with the needs of patients and their advocates.**
 - The intended use of information is to inform the content of the *For Patients* website and the design of FDA Patient Listening Sessions. Both tools will increase the ease, efficiency, and effectiveness with which patients can engage with the FDA and with which the FDA can engage patients for input on appropriate topics, encouraging two-way communication.
 - The information we gather regarding the *For Patients* website will reveal what users and potential users want, expect from, and are currently able to achieve by accessing the FDA website. In order to best serve patient needs, PAS will have patient stakeholders review and provide feedback on website structure, content and patient-friendly language. The information will reveal: (i) content or feature gaps on the website; (ii) problems with information architecture or how the content on the site is structured and how pages are laid out relative to one another; (iii) problems with how users engage with the structure; and; (iv) problems with the quality and accessibility of the content. These content gaps, information architecture problems, and navigation and accessibility problems will inform updates for the website.
- **Build on the existing model, understand what aspects of the current FDA Patient Listening Session program work well, and determine, through engagement with participants (patients, caregivers, and their advocates) a list of recommendations to enhance the sessions' value moving forward.**
 - The feedback from the FDA Patient Listening Sessions will reveal what participants expect and want from the Patient Listening Sessions and will include an assessment of the experience itself. This information will inform concrete recommendations on how to improve the structure and format as well as the content intended to be captured through the FDA Patient Listening Sessions.
 - The information from the follow-up survey which is distributed to patient and caregiver participants of FDA Patient Listening Sessions will inform PAS staff about the level of satisfaction that participants have post-participation. The survey can be used to identify whether there are additional needs patients may have and can inform future communications and any follow-up.

3. Description of Respondents

The respondents will be patients, caregivers, patient groups, and patient advocates. Specifically, potential, or historical users of the *For Patients* website and either historical or prospective participants in FDA Patient Listening Sessions.

4. How the Information is Collected

The information regarding the *For Patients* website and FDA Patient Listening Sessions program will be collected via customer satisfaction surveys. FDA Patient Affairs Staff will collect the information. The information regarding *For Patients* will be captured through retrospective and prospective interviews that focus on users' experience navigating the website. Information for the Patient Listening Sessions will be collected via a web-based program (Qualtrics) and telephone.

The Qualtrics survey link will be distributed via email to those who participated in each FDA Patient Listening Session.

The information gathered will be qualitative in nature, focusing on the expectations, needs, opinions, and utility of the experiences. The information will be complemented by evaluative metrics on understandability, utility, and experience.

In addition, open-ended questions will allow us to gather more qualitative information to have a better understanding of the user’s or participant’s needs and develop more specific recommendations for either the *For Patients* website or for the FDA Patient Listening Sessions.

We will conduct a total of 14 individual assessments or interviews for the *For Patients* website analysis and up to 128 individual assessments for the FDA Patient Listening Session program.

Materials for Information Collection:

Appendix 1: <i>For Patients</i> website Interview Guide
Appendix 1a: Consent for Website Interview Participants
Appendix 2: Post Patient Listening Session Survey for Patient/Caregiver Speakers

5. Confidentiality of Respondents

We will use the OMB language provided when we collect information from respondents:

“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-respondents), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.”

We will also use the following language for any information collected by Qualtrics web-based program:

This survey is hosted on the Qualtrics website. By completing this survey, you are agreeing to the Qualtrics Privacy Policy. The answers that you provide to this survey are provided to the FDA Patient Affairs Staff for the purpose of improving the Patient Listening Session program. When your answers are transferred to the FDA Patient Affairs Staff, your data (answers) are subject to the FDA Third-Party Websites and Applications Privacy Policy.

6. Amount and Justification for Proposed Incentive

No incentives will be used.

7. Questions of a Sensitive Nature

No questions of a sensitive nature will be included.

8. Description of Statistical Methods

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. We will use a database of known patient and patient advocate contacts maintained by the Patient Affairs Staff to identify eligible individuals for the *For Patients* website analysis; no screening will be necessary, as individuals are known to the FDA. Individual assessments will be conducted to meet target numbers as defined below.

9. Burden

Type of information collection/Category of Respondent	No. of Respondents	Participation Time (minutes)	Total Burden (hours)
Individuals or Households: <i>For Patients</i> website assessment	14	60	14
Individuals or Households: Post Patient Listening Session Survey for Patient/Caregiver Speakers	128	5	11
Totals	142	65	25

10. Date(s) to be Conducted

Calendar Year 2024.

11. Requested Approval Date

March 2024

12. FDA Contacts

Program Office Contact	FDA PRA Contact
Andrea C. Furia-Helms, M.P.H. Director, Patient Affairs Staff Andrea.Furia@fda.hhs.gov Office of Clinical Policy and Programs Office of the Commissioner 301-796-8455	JonnaLynn Capezzuto Director, Paperwork Reduction Act Staff jonnalynn.capezzuto@fda.hhs.gov Paperwork Reduction Act Staff Office of Enterprise Management Services Office of Operations 301-796-3794

Appendix I: *For Patients Website* Interview Guide

PRA Statement

OMB Control No. 0910-0697

Expiration Date: 01/31/2027

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 01/31/2027. The time required to complete this information collection is estimated to average 60 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

Hi, *name of participant*. My name is _____ and I'm with FDA's Patient Affairs Staff. 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 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 Patient Affairs Staff will make updates to our website so it is more "patient friendly."

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 FDA staff 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 a website 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 website? *(e.g., request information, post a comment, sign up for meetings, etc.)* What tasks might you be able to complete on the website?

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 AND FEEDBACK

*Click on the bookmark for the **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?

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. If you think of any additional information you'd like to share or have any questions, please contact us patientaffairs@fda.gov.

Appendix II: Post Patient Listening Session Survey for Patient/Caregiver Speakers

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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.

Background

Introduction and context: Patient Affairs would like to better understand the experiences and perspectives of the patients and caregivers who participate in FDA Patient Listening Sessions.

Objectives: We are trying to understand what aspects of the current Listening Session design work well and where there may be opportunities for improvement to maximize the usefulness of Patient Listening Sessions to both FDA staff and patients, caregivers, or their advocates. The survey can be used to measure participant's satisfaction in participating in an FDA Patient Listening Session.

Method of distribution: We will distribute this survey after the completion of each Patient Listening Sessions, both internally and externally requested. The Qualtrics survey link will be distributed via email to those who participated in each FDA Patient Listening Session.

Post Patient Listening Session Survey for Patient/Caregiver Speakers

Thank you for participating in this brief survey!

We are working to improve the Patient Listening Session program. This is voluntary survey. If you are comfortable, we welcome your feedback to these questions as well as any other aspect of the session not mentioned in the survey. We encourage you to forward this survey to the other speakers, as we would be very interested in learning how we could improve their experience as well. Completing the survey is completely optional.

This survey is hosted on the Qualtrics website. By completing this survey, you are agreeing to the Qualtrics Privacy Policy. The answers that you provide to this survey are provided to the FDA Patient Affairs Staff for the purpose of improving the Patient Listening Session program. When your answers are transferred to the FDA Patient Affairs Staff, your data (answers) are subject to the FDA Third-Party Websites and Applications Privacy Policy.

- o Yes – I acknowledge the information above and I would like to complete the survey.
- o No – I do not wish to be subject to the Qualtrics Privacy Policy or the FDA’s Third-Party Websites and Applications Privacy Policy. I understand that by selecting this choice, I will not be able to complete this survey.

Select the degree to which you agree or disagree with the statements below on a scale of 1 to 5, with 5 being Strongly Agree and 1 being Strongly Disagree.

	Strongly Disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
The FDA heard my perspective during the Listening Session.	0	0	0	0	0
The Listening Session was valuable.	0	0	0	0	0
I was comfortable with sharing my experience with FDA.	0	0	0	0	0

What could be improved in preparation for a Listening Session?

Is there anything else you would like to share with FDA Division Staff about your experience with your disease or health condition?

We thank you for your time spent taking this survey.
Your response has been recorded.