Cognitive Interview Guide: Web Content About Recently-Approved Medical Devices

Color Key:

Purple – Section headings and titles

Black –Text for interviewer to read

Red – Interviewer instructions (not to be read aloud)

Green – Research questions (for interviewer's information, not to be read aloud)

Introduction

Hello, my name is [INSERT INTERVIEWER NAME]. I work for Westat, a research company in Rockville, Maryland. Thank you for taking the time to be a part of this study.

Westat is conducting this study, which is sponsored by the U.S. Food and Drug Administration (or FDA), to see what people think about health information related to medical products.

In a moment, I will give control of the screen to you so you can look at a website. After you look at the website, I will ask you some questions on your thoughts and feelings about the information. Any ideas you have are okay.

IF PARTICIPANT CANNOT ACCESS WEBSITE OR USE SCREENSHARING, RESCHEDULE INTERVIEW.

Informed Consent

Before we get started, there are a few things I want to go over. Your participation in this interview is voluntary, and you don't have to answer any questions you prefer not to. It is also okay if you want to stop after we start. Just let me know.

All of your answers and everything you say will be kept secure to the extent permitted by law. This means we will not share your name or contact information. The interview will take about 45 minutes and you will receive $50 as a token of appreciation.

We would like to record this conversation to make sure we hear everything you say correctly. Please speak clearly and loudly. Also, please minimize background noise by finding a quiet location away from other people and distractions. If you haven't already, please silence your cell phone and other devices.

Only the research team working on this project will be able to listen to the recording and see our notes. Your name will not be linked to any of your responses, though we may include quotes that you provide in our reports. The recordings and our notes will be destroyed after we finish the project.

IF FDA STAFF ARE ON THE PHONE: I also want you to know that a couple members of the FDA research team are listening to this interview so they can hear directly from you.

Any questions? Is it okay if I record the interview? IF NO, TERMINATE.

TURN ON RECORDER. The date and time is _____. Now that I am recording, I want to ask again, is it okay if I record this interview?

Research Questions

Main Landing Page and Approvals by Year Page

1. How well does the landing page meet participants' expectations?
2. Is the landing page text clear, understandable, and well organized?
3. How would participants attempt to find information about a specific device?
4. What improvements do participants suggest for the landing page?

Information About Recently-Approved Devices

5. What are the main message(s) that participants get from the information?
6. How well do participants think the information explains both the benefits and the risks?
7. How clear and understandable is the text to participants? What words or phrases are confusing and what suggestions do participants offer for replacing them?
8. What information do participants find useful? Not useful? Repetitive?
9. What information do participants say is missing or would be helpful to add?
10. Are the question headers the ones that participants want answered?
11. How well do participants think the content is organized?
12. How do participants' reactions differ across the reviewed examples?
13. What suggestions do participants offer for improving the information?

Background Questions

To start, I have a few general questions.

FOR DIABETIC PARTICIPANTS
You told us when you volunteered for this interview that you have been diagnosed with diabetes or high blood sugar? Is this correct? IF NO, TERMINATE.
- How do you monitor your blood sugar? IF NEEDED, Do you prick your finger and use test strips, use a glucose meter, or wear a device with a sensor under your skin?
    - o IF WEARS DEVICE, Is this a continuous glucose monitoring device, or CGM? Do you happen to know the name of your device or who makes it? What else do you know about the device you wear? IF NEEDED, What are the benefits and the risks of the device you wear?
        - ▪ Did you get information about your device *before* you decided to wear it?
        - ▪ IF YES: Where did you get your information about the device? IF NEEDED, From your health care provider, from the Internet, or somewhere else?
            - • IF HCP, What conversations have you had with your health care provider about the device you wear? Did your health care provider recommend you monitor your blood sugar this way? Why was that?
            - • IF WEBSITE, From which websites have you gotten information about wearable devices for monitoring blood sugar? IF NEEDED, Was it the device manufacturer's website, a health advocacy group website, a government website, or something else?
    - o IF NOT WEARING DEVICE, What do you know about wearable devices for continuous glucose monitoring? IF NEEDED, What are the benefits and the risks of these types of devices?
- What questions do you have about wearable devices for continuous glucose monitoring?
- If there was a website about the newest medical technology available, what is the most important information you would want to find there about wearable devices for continuous glucose monitoring? IF COST, What else?

FOR PARTICIPANTS WHO HAVE OR CONSIDERED DERMAL FILLERS
You told us when you volunteered for this interview that you have had or considered cosmetic treatment that involves drug or dermal filler injections to give your face a smoother or fuller appearance. Is this correct? IF NO, TERMINATE. Have you already had an injection, or are you still considering whether to get an injection?
- o IF HAD INJECTION, Do you recall what kind of injection you had? IF NEEDED, Was the injection a drug, like Botox, or an injectable gel implant? Do you happen to know the name of your injection or who makes

it? What else do you know about the injection? IF NEEDED, What are the risks with these types of injections?

- Did you get information about your injection *before* you had it?
- IF YES: Where did you get your information about the product you had injected before the procedure? IF NEEDED, From your health care provider, from the Internet, or somewhere else?
  - IF HCP, What conversations have you had with your health care provider about the product you had injected? Did your health care provider recommend the injection? Why was that?
  - IF WEBSITE, From which websites have you gotten information about the product you had injected? IF NEEDED, Was it the manufacturer's website, a cosmetic surgery website, a government website, or something else?
  o IF CONSIDERING AN INJECTION, What do you know about dermal fillers, also known as injectable gel implants? What are the risks with these types of injections?
- What questions do you have about dermal fillers?
- If there was a website about the newest medical technology available, what is the most important information you would want to find there about dermal fillers? IF COST, What else?

FOR PARTICIPANTS WHO WEAR EYEGLASSES OR CONTACTS
You told us when you volunteered for this interview that you wear eyeglasses or contact lenses to see things in the distance. Is this correct? IF NO, TERMINATE. Do you currently wear contacts or do you only wear glasses?
  o IF WEARS CONTACTS, What kind of contacts do you wear? IF NEEDED, Do you happen to know the name or who makes them? Are they soft contact lenses, or are they hard or rigid gas permeable (RGP) lenses? Are they disposable or made for extended wear? What else do you know about your contacts? IF NEEDED, What are the risks with wearing these types of contact lenses?
- Did you get information about your contact *before* you started wearing them?
- IF YES: Where did you get your information about the type of contact lenses you wear now? IF NEEDED, From your doctor, from the Internet, or somewhere else?
  - IF HCP, What conversations have you had with your doctor about your contact lenses? Did your doctor recommend the contact lenses? Why was that?
  - IF WEBSITE, From which websites have you gotten information about the contact lenses? IF NEEDED, Was it the manufacturer's website, a store's website, a government website, or something else?

- What questions do you have about soft disposable contact lenses?
- If there was a website about the newest medical technology available, what is the most important information you would want to find there about soft disposable contact lenses? IF COST, What else?

ALL PARTICIPANTS

The FDA provides information about newly approved medical products like [glucose monitors OR dermal fillers OR contact lenses], and now I'd like to ask you some questions about that. I am going to share my screen with you. Do you see a page titled "Recently-Approved Devices?" This is a page on FDA's website. Please take a minute to read only this page **without clicking any of the links that take you to different pages, which we'll look at later**. I will give you control of the screen so you can review at your own pace. [HAND CONTROL TO PARTICIPANT] When you finish, I will ask you some questions about the information.

CHECK IN AFTER 1 MINUTE. ALLOW 1 MORE MINUTE IF NEEDED.

IF RESPONDENTS NAVIGATE AWAY, DIRECT THEM BACK TO THE PAGE FOR

NOW AND INFORM THEM THAT THEY MIGHT LOOK AT OTHER PAGES LATER.

CONCURRENT OBSERVATIONS/INSTRUCTIONS.
NOTE ANY OF THE FOLLOWING BEHAVIORS TO RECORD IN NOTES OR PROBE ON RETROSPECTIVELY:
- Any verbal reaction to statements in the information.
- Any verbal expressions of confusion, surprise, discomfort, offense. Note which statements evoked any of these reactions.

Recently-Approved Devices Page

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.

What are your overall thoughts about what you see here on the first page?

How easy or difficult is it to understand the information on this first page?
- Are there any words or phrases that confuse you or that you aren't sure of? IF NEEDED, How could that be stated more clearly?

What does it look like you can do on this webpage?
- If you wanted to search for the newest information about [glucose monitors OR dermal fillers OR contact lenses], how would you do that? NOTE WHETHER PARTICIPANTS CLICK INTO DEVICE APPROVALS BY YEAR, TRY TO USE THE SEARCH FUNCTION IN THE UPPER RIGHT CORNER, OR SEEM CONFUSED OR FRUSTRATED ABOUT HOW TO SEARCH.

What thoughts do you have about the approvals being listed by year? IF NEEDED, Do you like that way of listing the approvals or do you think they should be listed some other way?

Go ahead and click on 2022 Device Approvals.

2022 Device Approvals Page

What are your overall thoughts about what you see here on this page?

What do you like about this page and why?

What don't you like and why?

Is this the information you expected to see?
- Can you tell me more about that?
- What other information would you have liked to see?

How easy or difficult is it to understand the information on this page?
- Are there any words or phrases that confuse you or that you aren't sure of? IF NEEDED, How could that be stated more clearly?

What are your thoughts on the way this page is organized?

Again, if you wanted to search for information about [glucose monitors OR dermal fillers OR contact lenses], how would you do that?
- IF NOT NOTICED, There's a couple search functions on this page, one in the top right corner and another just above the table. Would you expect the search results from both of these search functions to be the same or different? Why is that?
- IF NOT NOTICED, Each of the column headers in the table has little arrows beside them. How useful are those arrows?
- How else could this table be made easier to search or scan?

ASK PRIOR TO VIEWING COMMUNICATIONS. RECORD RESPONSES SO YOU CAN REFER TO THEM LATER.
- FOR DIABETIC PARTICIPANTS, What would you expect to see if you clicked the communication about the Eversense glucose monitor dated 2/10/2022 [WILL NEED TO SCROLL TO PAGE TWO]?

- FOR PARTICIPANTS WHO HAVE OR CONSIDERED DERMAL FILLERS, Let's go back to the previous page titled "Recently-Approved Devices." Please click 2021 Device Approvals. What would you expect to see if you clicked the communication about the RHA Redensity dermal filler dated 12/22/2021?

- FOR PARTICIPANTS WHO WEAR EYEGLASSES OR CONTACTS, Let's go back to the previous page titled "Recently-Approved Devices." Please click <u>2019 Device Approvals</u>. What would you expect to see if you clicked the communication about the <u>MiSight contact lenses dated 11/15/2019</u>?

Please go ahead and click the link to that communication. Take a minute to read this page **without clicking on anything**. When you finish, I will ask you some questions about the information.

CHECK IN AFTER 2 MINUTES. ALLOW 1 MORE MINUTE IF NEEDED.

IF PARTICIPANTS NAVIGATE AWAY, DIRECT THEM BACK TO THE PAGE.

Product-Specific Pages

TO BE ADMINISTERED AFTER RESPONDENT COMPLETES HIS/HER REVIEW.

In your own words, what is the overall, main message of what you've just read?
- Why do you think FDA is telling you this information?

How does what you see on this page compare with what you expected to see? IF NEEDED: Is this the information you expected to see? If not, what's missing? Is the information presented or explained in a way that makes sense to you? Why or why not?

What are your thoughts on the way this page is set up?
- The page is grouped by questions. Are these the questions you would want answers to if you were thinking about using a new [glucose monitor OR dermal filler OR type of contact lenses]? IF NO, What questions would you want answered and why?
  - o Would you change the order of any of the questions? How would you reorder the sections and why?
  - o Were there any answers that did not address the question as completely as you would have expected or that raised additional questions or concerns?
  - o Are there any questions that you think are NOT needed or can be removed? IF YES, Which questions and why do you think they are unnecessary?

How easy or difficult is it to understand the information?
- Are there any words or phrases that confuse you or that you aren't sure of? IF NEEDED, How could that be stated more clearly?
  - o The title at the top of the page ends with the letter "P" followed by several numbers. What do you think that is or why it might be there?

o   Toward the top of the page, there is information about the "PMA Applicant." What does this mean to you?

After reading this information, what new information have you learned about this product?

Does anything you've read on this page concern you? Why is that?

How well do you think the information explains the risks of using this product?

How well do you think the information explains the benefits of using this product? IF NEEDED, Does the information explain the risks and benefits equally, or does the emphasis seem to be on one more than the other?

How trustworthy is the information on this page? What makes you say that? IF NEEDED, What could be done to increase trust in this information?

How useful is this page to you?
- Which parts are most useful to you?
- Which parts are the least useful to you?

What do you think about the images on this page? How well do they go with the content? Would you suggest using any different images instead?

What additional questions do you have after reading this page?

After reading this page, what would you do? IF NEEDED, Ignore it, share it, talk with your health care provider about it, etc.

WRAP-UP

Do you have any other suggestions for improving any of the webpages I shared with you today?

PROBE ON ANY OUTSTANDING ISSUES FROM OBSERVATION (INFORMATION THAT RESPONDENT SEEMED CONFUSED ABOUT).

CLOSING

IF OBSERVERS ARE PRESENT, CHECK TO SEE IF THEY HAVE FURTHER QUESTIONS.

Those are all the questions I have for you. Is there anything else you would like the FDA to know about these web pages or communicating about [glucose monitors OR dermal fillers OR contact lenses]?

DISCUSS ANY RESPONDENT COMMENTS.

Thank you for your time.
STOP TAPE RECORDER.