

Appendix D: Moderator's Guide

OMB Control No: 0910-0695

Expiration Date: March 31, 2024

Paperwork Reduction Act Statement: 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 number for this information collection is 0910-0695. The time required to complete this information collection is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRStaff@fda.hhs.gov.

Prescription Drug Use Related Software (PDURS) Study Focus Groups with Consumers and PCPS Draft Moderator's Guide 60 Minutes

Introduction [3 minutes]

Thanks for joining us today. I'm _____, and I'm from Westat. We're a research organization based in Maryland. We are conducting these discussions on behalf of the U.S. Food and Drug Administration (also known as FDA). We are holding discussions around the country to better understand [INDIVIDUALS WHO HAVE BEEN DIAGNOSED WITH DIABETES OR PRIMARY CARE PROVIDERS] experience and perceptions of prescription drugs. Your insights are very important to us and your time today is appreciated. We will have about 60 minutes for our discussion.

Informed Consent

Before we begin, I want to review a few things with you. First, you all should have received a copy of the informed consent form when you received the confirmation email to participate in this discussion. Some of you may have read it, but I want to go through the key points of that form and see if you have any questions.

- Your participation is voluntary. You can leave at any point in the discussion. In addition, if at any point you feel uncomfortable with my questions, simply let me know that you prefer not to answer.
- We would like to audio and video record this discussion. The audio recordings will be transcribed so that we don't miss the important things that you say.
- We will be writing up our findings from all of the groups in a report for FDA. When we do this, we may use a quote from someone, but we will never include your name or any

identifying information about you. We believe the risks to you from participating are low. There is a slight risk that your personally identifiable information may be shared, but this is unlikely because we only have your first name. We ask that everyone only use first names when addressing others or referring to yourself or others in your life.

- If there are others present in your household during this discussion, please make sure you wear headphones/earbuds and position the screen so that others can't see.
- Our discussion today will take about an hour and you will receive [**\$75 for consumers OR \$250 for PCPs**] as a token of appreciation for your participation.
- Also some of our colleagues from Westat and FDA are observing today's focus group. They may have additional questions for you, so towards the end of our discussion I'll check in with them.

Does anyone have any questions about what I just reviewed? [\[ANSWER ALL QUESTIONS\]](#)

Alright, now I just want to review a few ground rules for our discussion.

- Please have your cameras turned on at all times while you're in the group. It's okay to turn them off if you have to step away.
- There are no right or wrong answers in today's discussion. We want to know your honest opinion and experiences and it is Ok to disagree with each other.
- I do not work at FDA and I'm not an expert about the topics we are going to discuss today, so you may have questions that I can't answer. I will make sure the people at FDA who are working on the project are aware of the questions you have.
- Everyone's participation is important; we want to hear from everybody. You also don't have to wait for me to call on you if you have something to say; I would ask that you speak one at a time, though, so that I can hear what each of you has to say. If you prefer, there is a virtual hand you can raise that can be found under the reactions tab.
- Please also make sure you know where your mute button is—if you feel like there is some unexpected disruptive background noise, I ask that you mute yourself, but unmute it when you want to say something.

Do you have any questions before we begin?

Introductions of Participants [5 minutes]

I'm here to facilitate and guide our discussion but I mainly want to hear from you, about your experiences and opinions. Before we begin, though, let's introduce ourselves; please tell me your first name and something unique about you - an interesting hobby, somebody famous you've met, your 15 minutes of fame. [Moderator should also participate in this exercise.]

Medication Adherence and Familiarity of PDURS [5 minutes]

Consumers:

All of you mentioned during your qualifying interview that you have been diagnosed with diabetes by a healthcare provider.

1. What if anything do you do to make sure you take your medications as prescribed, either for diabetes or other health condition? [Probe: do they use a timer, an app, something to measure the right dose?]
2. In addition to traditional medicines, like insulin, there are new products called “digital medicines” or “digital pills” or “smart pills” what have you heard about them?
 - o Have you or a family member used a digital medicine? IF YES: Can you tell me about it?

PCPs:

1. What strategies or tools do you provide to your patients with diabetes to improve medication adherence?
2. There are new products called “digital medicines” or “digital pills” or “smart pills” what have you heard about them?
 - a. Have you had any patients use any of these digital medicines? IF YES: Can you tell me about it?

Reactions to PDURS Description [25 minutes]

Ok, now I'm going to share my screen and have you read a short description of prescription drugs that contain technology or software.

To help people take medicines as prescribed, new products are being developed that add technology to traditional medications. This includes pills with a microchip the size of a sand particle that sends a Bluetooth signal once the pill has been taken. Products also include trackers on dispensers for injectable medications, such as insulin, indicating the injection was given. These products are being developed for diabetes and other conditions such as HIV, schizophrenia, renal transplants, and high blood pressure.

1. What are your initial reactions to these type of products? [NOTE: Some participants may have strong reactions. After sharing their initial reactions be mindful to hear reactions from most participants and keep the conversation moving.]

- o What do you like about them?
 - o What do you dislike about them?
- 2. What questions do you have about these products?
- 3. Who do you think would benefit from these products?
 - o For PCPs: What chronic health conditions might a product like this help with?

Consumers:

1. How might a product like this help you?
 - o Do you think using a medication with this technology would control your diabetes better than what you are currently prescribed? Why or why not?
2. How interested would you be in using a product like this to control your diabetes or manage another health condition?
 - o How would your interest change if in the description of the product it said research has shown it has helped people take the medication as prescribed?
 - o How would your interest change if in the description of the product it said there was no information available to show it helps people take the medication as prescribed? [Probe: What does no information mean to you?]
3. What concerns, if any, would you have about using a product like this?
 - o [If safety is mentioned as a concern] What would convince you it was safe to use?
 - o [If privacy/trust/relationship with healthcare provider is mentioned as a concern] Can you say more about that?
4. If you were considering using a product like this what information would you want to know?

PCPs:

1. How do you think a product like this could help patients with diabetes?
 - o Do you think a medication with this technology would help patients manage their condition better than traditional medications? Why or why not?

2. How interested would you be in prescribing a product like this to your patients with diabetes and other health conditions?
 - o How would your interest change if in the description of the product it said research has shown it increased medication adherence?
 - o How would your interest change if in the description of the product it said there was no information available to show it increased medication adherence?
[Probe: What does no information mean to you?]

3. What concerns, if any, would you have about prescribing a product like this to your patients?
 - o [If needed] How do you think recommending or discussing a product like this would impact your relationship with a patient?
 - o [If safety is a concern] What would convince you it was safe to prescribe?

4. If you were considering prescribing a medication like this what information would you want to know?
 - o What information would you share with your patients?

False Close [5 minutes]

That's all the questions I have. I am going to check in with my colleagues to see if I missed anything. I'll be right back.

Close [2 minutes]

Do you have any questions for me or any additional feedback that you'd like to provide? Thank you very much for your time today. Your feedback is very much appreciated. Plaza Research will be providing your incentives, so please reach out to them if you have any questions.