**FDA Caregiver Study**

*Phase 1 – Focus Group Moderator Guide*

*Caregiver Version*

The focus group will be comprised of the following steps:

1. **Consent Form**: Ask participants to read and sign the consent form.
2. **Welcome**:
	1. **Welcome -** The moderator will welcome the participants and explain the purpose of the focus group session.
	2. **Ground rules -**The moderator will provide guidance to ensure that participants are allowed to speak without interruption by other participants.
3. **Warm-up**: Participants will introduce themselves and provide a little information about themselves**.**
4. **Discussion:** In the focus group, participants will discuss the following topics:
5. Role that partners play in treatment decisions, particularly for prescription drugs
6. What prompts patients and partners to discuss prescription drugs
7. What patients and partners discuss related to prescription drugs
8. Social context in which partners view drug advertisements
9. How partner presence affects drug ad viewing
10. **Closing**

**Welcome (5 min)**

Thank you for coming today. I’m \_\_\_\_\_, and I’m from RTI International. The purpose of this focus group is to learn more about how people make health decisions.

Your experience and perspectives are very important to us, and I genuinely appreciate your time today. This session will last about 90 minutes.

First, I want to cover two housekeeping items:

* **Audio Taping.** You have probably noticed the microphones in the room. They are here because we are audio taping today’s session. At the end of all our focus groups, we want to summarize our findings. I want to give you my full attention and not take a lot of notes, so I will refer to the tape when writing the summary.
* **Client Observation.** Behind me is a one-way mirror. Some of the people working on this project are observing this discussion so that they can hear your opinions. However, your identity and anything you say will remain confidential. Your names will not be given to anyone, and no one will contact you after this group is over. When we summarize these groups, we will not refer to anyone by name.

Before we begin, I want to review a few ground rules for today’s group discussion:

1. **Honest Opinions.** Most importantly, **there are no right or wrong answers**.We want to know your honest opinions, and those opinions might differ. This is fine. We want to hear your honest experiences and thoughts on the topics we discuss.
2. **Speaking.** Please try to **speak one at a time**. I may occasionally interrupt you when two or more people are talking in order to be sure everyone gets a chance to talk and that we capture your responses accurately.
3. **Cell Phones.** As a courtesy to everyone, **please silence or turn off your cell phones, PDAs, and pagers**.
4. **Restrooms.** If you need to go to the **restroom during the discussion, please feel free to leave**; however, I’d appreciate it if you would go one at a time.
5. **Questions.** Do you have any **questions** before we begin?

Warm up (5 min)

I would like to begin our discussion by asking you to introduce yourself. Please tell us:

* Your first name
* Where you grew up
* The most important thing you do to stay healthy

**Partner Role in Treatment Decisions (25 minutes)**

For our first activity, I’m going to hand everyone a piece of paper. Everyone in this group was selected because your partner has been diagnosed with asthma, and we’d like to learn more about how you are involved in decisions about your partner’s asthma care.

Please think about the last time you were involved in a decision about your partner’s asthma care. This might be the decision to start or change medications, the decision to start a new behavior or change a behavior (e.g., exercise, quitting smoking), or the decision to find a new doctor. You may have been heavily involved or barely involved in this decision.

I’d like you to take five minutes to sketch out (a) all of the things you considered during that decision and (b) how important each of those things was to you. Things that were most important go on the inside circle, and things that were least important go on the outside circle. These may or may not be the same things that were important to your partner.

Let me give you an example…

[Distribute worksheet and black pen to each participant. Showcase example sketches on flipchart. Allot five minutes for exercise. ]

Now let’s take a look at the sketches you created. I’d like a few individuals to walk us through their sketches, and we can use those as a starting point for our discussion.

Please feel free to update or add to your sketch if our discussion gives you additional ideas or makes you realize that you considered other things in the decision.

[Collect black pens. Distribute red pen to each participant, which they can use to update the sketches.]

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| --- | --- |
| Question | Probes |
| 1. [Select 2-3 participants] Walk me through what things you considered in this decision about his/her asthma care.
 | * How were these different than the things your partner considered during that decision?
 |
| 1. [Open to entire group] When you and your partner make decisions about his/her asthma care, what are the most important things that you consider?
 | * What are the top three things that you consider?
* What things are not important to you in decisions about your partner’s asthma care?
 |
| 1. When it comes to decisions about your partner’s asthma care, what role (if any) do you play?
 | * What specifically do you do or say?
* How often do you suggest that he/she talk to their doctor?
* How often do you share your opinion about specific treatment options?
* How often do you seek additional treatment information for your partner?
 |
| 1. When you and your partner make decisions about prescription drugs for his/her asthma, what are the most important things that you consider?
 | * What things are not important to you in these prescription drug decisions?
 |
| 1. When it comes to decisions about prescription drugs for your partner’s asthma, what role (if any) do you play?
 | * What specifically do you do or say?
* How often do you suggest that your partner talk to his/her doctor about prescription drug options?
* How often do you share your opinion about specific prescription drugs?
* How often do you seek additional prescription drug information for your partner?
* How does your partner usually react when you do these things?
 |
| 1. What (if anything) makes it difficult for you to participate in your partner’s asthma care decisions?
 | * Tell me about a time when you wanted to be involved in a decision about your partner’s asthma care but were not.
* Why weren’t you involved?
* Tell me about a time when you shared your opinion about your partner’s asthma care and it was not considered.
* Why wasn’t your opinion considered?
 |

**Prescription Drug Discussions – Catalysts (20 minutes)**

Next, I’d like to talk more about when and why you and your partner discuss prescription drugs for asthma.

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| --- | --- |
| Question | Probes |
| 1. When do you typically discuss prescription drugs for asthma with your partner?
 | * What specific events spark or prompt those discussions?
* What about an upcoming doctor’s appointment?
* What about new or worsening symptoms?
* What about hearing someone else’s experience with a drug?
* What about when you disagree with a choice he/she is making (e.g., behavior that seems risky)?
* What other events prompt you and your partner to talk about prescription drugs?
 |
| 1. What (if anything) makes it difficult to discuss prescription drugs with your partner?
 | * Tell me about a time when you wanted to be involved in a decision about your partner’s medications but were not.
* Why weren’t you involved?
* Tell me about a time when you shared your opinion about a prescription drug and it was not considered.
* Why wasn’t your opinion considered?
 |
| 1. Please think about the last time your partner talked to his/her doctor about a prescription drug for his/her asthma. How involved were you in that conversation?
 | * To what extent did you and your partner talk about the drug prior to the appointment?
* To what extent did you and your partner talk about the drug after the appointment?
* What specifically did you and your partner discuss?
 |
| 1. How often do drug advertisements on TV or in magazines prompt you and your partner to discuss prescription drugs?
 | * Why do these ads prompt a discussion?
* What types of drug ads are most likely to prompt a discussion with your partner? (For example, TV vs. print, real patient testimonial vs. celebrity endorsement, etc.)
* Do you usually discuss the ad itself or the drug being advertised?
* What would prompt you to share a drug advertisement with your partner (assuming they had not viewed the ad with you)?
 |

**Prescription Drug Discussions – Content (20 minutes)**

We’ve already spent some time talking about when you and your partner discuss prescription drugs. Now I’d like to learn more about the content of those conversations.

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| --- | --- |
| Question | Probes |
| 1. When you and your partner talk about prescription drugs, what specifically do you discuss?
 | * How often do you discuss drug risks or side effects?
* How often do you discuss drug benefits?
* How often do you discuss the different drug choices available?
 |
| 1. When you and your partner discuss prescription drugs, how often do you share a concrete recommendation?

(For example: “I think you should ask about Drug X” or “I think the side effects of Drug X are too serious for you to take it”.) | * What are some recommendations that you have given your partner?
* How often do you recommend that your partner talk to their doctor?
* How often do you recommend changing the drugs your partner uses?
 |
| 1. What do you find most helpful about discussing prescription drugs with your partner?
 | * What do you find least helpful about these discussions?
 |
| 1. Please think again about prescription drug ads that you see on TV or in magazines.

When you and your partner talk about a drug ad, what specifically do you discuss? | *Ad Characteristics** What parts of the ad do you discuss?
* How often do you discuss the health claims made in the ad (e.g., reduces asthma attacks)?
* How often do you discuss whether the information in the ad is accurate?
* How often do you discuss whether the drug is for someone like your partner?

*Drug Characteristics** How often do you discuss the drug’s risks and side effects?
* How often do you discuss the drug’s benefits?
* How often do you discuss how easy or difficult it might be to use the drug?
* What else do you discuss when talking about drug ads?
 |

**Social Context of Ad Exposure (10 minutes)**

Let’s switch topics a bit and talk about how you view advertisements for prescription drugs.

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| --- | --- |
| Question | Probes |
| 1. When and where do you typically see or hear drug ads in your daily routine?
 | * When you see these ads, do you pay attention to them? Why or why not?
* What are you usually doing when you come across these ads?
* Who are you usually with when you come across these ads?
* How do you view drug ads differently when you're in a public setting (e.g., subway, bus) versus a private setting (e.g., home)?
 |
| 1. How often is your partner with you when you encounter these drug ads?
 | * What are you and your partner doing when you come across these ads?
 |
| 1. Consider this situation: You’re watching TV alone and a drug ad comes on TV. What would happen?

Now imagine that you’re watching TV with your partner and a drug ad comes on TV. What would happen? | * How would your attention to the ad differ in these two situations?
* What else would be different in these two situations?
* What would your partner do in the second situation?
 |

**Closing (5 minutes)**

We’ve spent a lot of time talking today about how you and your partner discuss and make decisions about asthma. I’d like to ask just a few last questions as we wrap up today’s discussion.

|  |  |
| --- | --- |
| Question | Probes |
| 1. Overall, how involved do you want to be in your partner’s asthma care?
 | * How does this compare with how involved you actually are in your partner’s asthma care?
 |
| 1. Is there anything else we should know that we didn’t discuss today?
 |  |

Thank you again for participating in today’s group. Your input was extremely valuable, and we really appreciate your time.