

Oncology Indications

Endpoint Disclosure Focus Group Moderator Guide

A. WELCOME AND GROUND RULES

Thank you for taking the time to join us today. I am _____ from RTI, a non-profit research organization. This focus group is being sponsored by the Food and Drug Administration, or FDA. Our discussion will last about one hour. The purpose of this focus group is to ask you some questions about ads for drugs used to treat different types of cancer and get your thoughts about the ways that cancer treatments are talked about. **[FOR POST-TREATMENT GROUPS]** You all identified yourselves as having completed treatment for cancer, that is what you all have in common.

Before we start, I want to review a few important things.

- Your participation today is voluntary and you have the right to stop being in the focus group at any time.
- None of my questions are very personal, but you can choose not to answer any of them if you are uncomfortable. Just let me know that you prefer not to answer.
 - **[FOR POST-TREATMENT GROUPS]** You may choose to share information about your medical treatment or condition, but you don't have to. Either way, I want everyone to be comfortable sharing. We will all aim to be as supportive as possible of each other during this group.
- We are audio recording this discussion so that I can give you my full attention and not have to take notes. When writing up a summary of the focus groups, we will not include any information that could identify you. Your name, address, and phone number will not be given to anyone, and no one will contact you about this research after this group is over.
- I have colleagues listening to our discussion and taking notes behind the glass. At the end of our conversation, I may go into the back to see if there are any last-minute questions for you.
- We are also live-streaming our session so that other members of the research team who couldn't be here today can observe our discussion remotely.
- Anyone can speak, and I'd like to hear from everyone; you don't need to wait for me to call on you, just make sure you speak up and speak one at a time.
- Please set your cell phones to vibrate or turn them completely off. If you need to use the restroom, please feel free to step out and join us once you are done.
- I am not selling anything, I do not work for the people sponsoring this research, and I haven't created any of the things we'll look at, so don't hold back on giving me your honest opinions.
- If you disagree with anything that is said, I want to hear about it. If something is confusing, please let me know. Even if you are the only person in the room who feels that way—your opinion represents hundreds of people who are not in this room today.
- Most importantly, there are no right or wrong answers. None of these are trick questions. I want to know your opinions and about your experiences.
- I am not an expert about the topics we are going to discuss today or a medical doctor, so you may have questions that I can't answer. However, we do want to know about questions you have on the materials I'm presenting today. At the end of our discussion, I can give you a website address that may give you more information about some of the topics we've discussed.

Do you have any questions before we continue?

B. PARTICIPANT INTRODUCTIONS - WARM-UP

To start, I'd like to go around the room and introduce ourselves. When we get to you, please tell us:

- Your first name and
- One thing you like to do in your free time

C. TERMINOLOGY

I'd like to get your feedback on some medical terms you may or may not have heard before. Some of these terms relate to different diseases and conditions, but today we will be talking about these terms only as they relate to cancer, not any other diseases.

OVERALL SURVIVAL

The first one is "overall survival". We'll talk about it in a minute, but first, I'd like you to answer the 2 questions on page 1 of your workbook.

1. Have you heard the term "overall survival"? [MODERATOR PUT TERM ON FLIP CHART]

2.



Where have you heard this before? [PROBE: TV ads, HCPs, caregivers] [MODERATOR WRITE ANSWERS ON FLIP CHART]

3.

What does this term mean to you? Who would like to share what they wrote in their workbook? [MODERATOR WRITE ANSWERS ON FLIP CHART]

4.

[FOR POST-TREATMENT GROUPS] Did your doctor ever mention this term when discussing your cancer with you? If so, did they explain it? How did they explain it to you? What words did they use?

5. Here is a definition of overall survival. [MODERATOR SHOW DEFINITION ON FLIP CHART: *The length of time that patients are still alive after starting treatment.*] In the workbook, please turn to page 2 and answer the question.



6. What

- are your first thoughts about this definition?
7. What do you find confusing about this definition?
8. What information would help you decide whether to try a drug that can help improve overall survival?
9. Imagine that you had to explain the idea of overall survival to someone who may not understand or have heard of the term. How would you explain it?
10. [FOR POST-TREATMENT GROUPS] Did your doctor explain this idea in a different way? How did they explain it to you? What words did they use?

PROGRESSION-FREE SURVIVAL

Next, we are going to talk about the term “progression-free survival”. Please answer the questions on page 3 of your workbook and then we’ll discuss.

11. Have you heard the term “progression-free survival”? [MODERATOR PUT TERM ON FLIP CHART]
 - a. Where have you heard this before? [PROBE: TV ads, HCPs, caregivers] [MODERATOR WRITE ANSWERS ON FLIP CHART]
 - b. What does this term mean to you? Who would like to share what they wrote in their workbook? [MODERATOR WRITE ANSWERS ON FLIP CHART]
 - c. [FOR POST-TREATMENT GROUPS] Did your doctor ever mention this term when discussing your cancer with you? If so, did they explain it? How did they explain it to you? What words did they use?

Here is a definition of progression-free survival. [MODERATOR SHOW DEFINITION ON FLIP CHART: *The length of time after starting treatment that a patient lives with the disease but it does not get worse.*] In your workbook, please turn to page 4 and answer the question, then we’ll discuss.

12. What are your first thoughts about this definition?
13. What do you think when you hear “gets worse”? What does that mean to you?
14. What do you find confusing about this definition? What did you find clear? Specifically, what were you thinking about? [PROBE on whether they thought about symptoms]
15. If the definition was a little different and said “the length of time after starting treatment that a patient lives with the disease but it does not grow or spread further” what would that mean? The same meaning or different?
16. What do you think are the benefits or good parts of using a drug that improves progression-free survival?
17. What information would help you decide whether to try a drug that can help improve progression-free survival?

So, if a drug increases progression free survival that *might* mean that it could increase how long a patient lives, but there is no information available to say whether the drug will *actually* help them live longer. [MODERATOR SHOW CLARIFYING TEXT ON FLIP CHART]

18. Imagine that you had to explain the idea of progression-free survival to someone who may not understand or have heard of the term. How would you explain it?
19. [FOR POST-TREATMENT GROUPS] Did your doctor explain this idea in a different way? How did they explain it to you? What words did they use?

OBJECTIVE RESPONSE RATE

Next, we are going to talk about the term “objective response rate”. Go ahead and answer the questions on page 5 of your workbook and then we’ll discuss.

20. Have you heard the term “objective response rate”? [MODERATOR PUT TERM ON FLIP CHART]
 - a. Where have you heard this before? [PROBE: TV ads, HCPs, caregivers] [MODERATOR WRITE ANSWERS ON FLIP CHART]

- b. What does this term mean to you? Who would like to share what they wrote in their workbook? [MODERATOR WRITE ANSWERS ON FLIP CHART]
- c. [FOR POST-TREATMENT GROUPS] Did your doctor ever mention this term? If so, did they explain it? How did they explain it to you? What words did they use?

Here is a definition of objective response rate. [MODERATOR SHOW DEFINITION ON FLIP CHART]: *The proportion of patients whose tumor shrinks or who have a decrease in the number of detectable cancer cells in their body.* In your workbook, please turn to page 6 and answer the question, then we'll discuss.

21. What are your first thoughts about this definition?
22. What do you find confusing about this definition?
23. What information would help you decide whether to try a drug that can help improve objective response rate?

So, if a drug increases objective response rate that *might* mean that it could increase how long a patient lives, but there is no information available to say whether the drug will *actually* help them live longer.

[MODERATOR SHOW CLARIFYING TEXT ON FLIP CHART]

24. Imagine that you had to explain the idea of objective response rate to someone who may not understand or have heard of the term. How would you explain it?
25. [FOR POST-TREATMENT GROUPS] Did your doctor explain this idea in a different way? How did they explain it to you? What words did they use?

D. Endpoint Exercise

Next, I'd like you to imagine that you see the following claims in a television ad for a prescription medication for treating cancer. I'm going to show you two different claims and then we will discuss your reactions to them. In both of these example claims, Drug X is for patients with a cancer called multiple myeloma.

[MODERATOR SHOW ON WHITEBOARD: *Drug X increased the time patients lived without their multiple myeloma getting worse or passing away from any cause.*] [PFS]

1. What is the main idea the advertiser is trying to get across here?
2. Which of the 3 terms we discussed would this be an example of? What makes you say that?
3. What questions come to mind when you see this statement?
4. What would be important to know about this treatment? What is missing from this statement?
5. What do you think are the likely benefits of taking this drug?
6. Imagine you wanted to tell your friend or family member about this drug, but you wanted to make sure they knew that the information above does not necessarily mean that the drug will help them live longer. Go ahead and turn to page 7 in your workbook and write down how you'd explain that.

[MODERATOR SHOW ON WHITEBOARD: *When taking Drug X, more than half of women saw their tumors shrink: 55.4% of women on Drug X + Drug Y saw their tumors shrink vs 40.2% on Drug Y.*] [ORR]

7. What is the main idea the advertiser is trying to get across here?
8. Which of the 3 terms we discussed would this be an example of? What makes you say that?
9. What questions come to mind when you see this statement?
10. What would be important to know about this treatment? What is missing from this statement?
11. What do you think are the likely benefits of taking this drug?
12. Imagine you wanted to tell your friend or family member about this drug, but you wanted to make sure they knew that the information above does not necessarily mean that the drug will help them live longer. Go ahead and turn to page 8 in your workbook and write down how you'd explain that.

E. CLOSING

[FALSE CLOSE—TIME PERMITTING] We are almost done. I'm going to check with my colleagues to see if they have any other questions. [MODERATOR CHECKS FOR EXTRA QUESTIONS]

I want to thank each of you for coming and for participating today. These conversations will help us understand what information people need to make important health and treatment decisions for themselves and their family. We are looking to see how we can present this information so that it's clear and people can feel confident and informed in their decisions. I mentioned earlier that I would give you a website if you want more information about some of the terms we talked about: www.cancer.gov [MODERATOR WRITE ON FLIP CHART] or talk to your healthcare provider.