

FDA Biosimilars Study

Interview Guide (Phase 2)

Interview will comprise the following elements:

- I. **Welcome:**
 - a. **Informed consent**—Brief review of consent form. Obtain participant's written consent.
 - b. **Overview**—Thank participant for enrolling and explain purpose of the interview.
- II. **Knowledge and Information Needs.** Determine participant's current knowledge of and information needs related to biosimilars.
- III. **Message and Materials Testing.** Solicit participant's feedback on draft messages and materials. Specifically, interview will seek to assess:
 - a. **Comprehension.** Do participants understand main points of each message/material?
 - b. **Clarity.** Are messages/materials clear and understandable? Do they use clinical terms and professional jargon only when necessary?
 - c. **Believability.** Do participants trust and believe the information in the messages/materials?
 - d. **Design.** Does each material's design and layout clearly convey the desired information?
 - e. **Delivery.** How would participants prefer to receive the messages/materials?
- IV. **Prescribing / Dispensing Attitudes.** Assess participant's comfort with prescribing or dispensing biosimilars after reading the messages/materials.
- V. **Closing.** Ask for final thoughts and thank participant for his/her time.

WELCOME

Welcome (5 Minutes)

Thank you for coming today. I'm _____, and I'm from RTI International, a nonprofit research organization. The purpose of today's interview is to get your feedback on educational materials that are being developed to help physicians and pharmacists learn more about biological products. Your perspective is very important to us, and I genuinely appreciate your time today. This session will last about one hour.

I want to let you know upfront that I'm not a medical professional, and I am not an expert on biological products. Instead, my role is to facilitate today's interview and ensure that we obtain your feedback on several materials.

Before we begin, I want to cover a few housekeeping items:

1. **Audio and Video Recording.** We're planning to audio and video record today's session. At the end of all our interviews, 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 recordings when writing the summary.

2. **Client Observation.** Some other team members are observing this interview online so that they can hear your opinions directly from you. However, your identity and anything you say will remain confidential to the extent permitted by law. Your name, address, and contact information will not be given to anyone, and no one will contact you after this interview is over. When I write a summary of the interviews, I will not refer to anyone by name.
3. **Honest Opinions.** Most importantly, **there are no right or wrong answers.** We want to know your honest opinion about the materials that we're reviewing today. We're going to review several materials—some of them you might like, others you might dislike. This is important for us to know.
4. **Cell Phones.** Finally, if you haven't already, **please silence or turn off your cell phone, PDA, and pager.** That way, we can focus on the materials without being interrupted.

KNOWLEDGE AND INFORMATION NEEDS (10 Minutes)

First, I'd like to learn more about your experience with and knowledge of biological products.

Questions

1. How often do you [prescribe / dispense] biological products in your practice?
2. Please tell me what you know or have heard about products called "biosimilars".
3. Now I'm going to present you with a list of topics related to biosimilars. Each topic is listed on its own card.

I'd like you to take a few minutes and organize the cards into a column based on which topics you're most interested in learning more about. Place the topic in which you're most interested at the top of the column and the topic in which you're least interested at the bottom.

[Card sort activity. Present participant with stack of 5-8 cards, each with a biosimilar-related topic (e.g., definition of biosimilars, approval process for biosimilars).]

Probes

- What conditions do you typically associate with biological products?
- In your opinion, what are the positive aspects of biological products?
- In your opinion, what are the negative aspects of biological products?
- What are the positive aspects of biosimilars?
- What are the negative aspects of biosimilars?
- Overall, do you have a positive or negative impression of biosimilars? Why is that?
- Tell me why you organized the topics the way you did.
- [First topic] Why did you want to learn more about this topic?
- [Last topic] Why were you least interested in this topic?

MESSAGE AND MATERIALS TESTING (40 Minutes)

Message Testing (10 Minutes per Message) [Repeat for each message]

Next, I'm going to hand you some information about biosimilar products. Even though it might feel odd, I'd like you to read the information out loud and then talk through your thoughts and reactions to the information out loud. Hearing your first reactions allows us to understand what comes to mind as you read the information and how we can improve it.

Here's the information I'd like you to read... [Present message to participant]

Questions

Probes

- | | |
|--|---|
| 4. What are your first thoughts after reading this information? | |
| 5. In your own words, what are the main messages contained in this handout? | <ul style="list-style-type: none">▪ What information was most important to you? Least important?▪ What else would you still like to know after reading this handout? |
| 6. [Comprehension of specific element / phrase] In your own words, what does the phrase “[insert phrase]” mean to you? | <ul style="list-style-type: none">▪ How easy or difficult is it to locate [key message]? |
| 7. What information in this handout might your colleagues or staff find confusing? | <ul style="list-style-type: none">▪ How could we eliminate that confusion?▪ What terms or phrases might your colleagues or staff find confusing?▪ How could we explain those terms or phrases more clearly? |
| 8. Based on your own experience, how accurate is the information in this handout? | <ul style="list-style-type: none">▪ [If accurate] Why do you feel that it's accurate?▪ [If not accurate] What seems inaccurate? How could it be made more accurate? |

- 9. What did you like about this information?
 - What did you dislike about this information?
 - What would you change about this information to make it more useful?

- 10. How would you like to receive the information contained in this handout?
 - At what point in the [prescribing / dispensing] process would you like to have this information?

Materials Testing (10 Minutes per Material) [Repeat for each material]

Now I'm going to hand you a formal educational material about biosimilar products. As with the other handouts, I'd like you to read the material out loud and then talk through your thoughts and reactions to the material out loud.

Questions

Probes

- | | |
|--|---|
| <p>11. What are your first thoughts after reading this material?</p> | |
| <p>12. In your own words, what are the main messages contained in this material?</p> | <ul style="list-style-type: none"> ▪ What information was most important to you? Least important? ▪ What else would you still like to know after reading this material? |
| <p>13. [Comprehension of specific element / phrase] In your own words, what does the phrase “[insert phrase]” mean to you?</p> | <ul style="list-style-type: none"> ▪ How easy or difficult is it to locate [key message]? |
| <p>14. What information in this material might your colleagues or staff find confusing?</p> | <ul style="list-style-type: none"> ▪ How could we eliminate that confusion? ▪ What terms or phrases might your colleagues or staff find confusing? ▪ How could we explain those terms or phrases more clearly? |

15. Based on your own experience, how accurate is the information in this material?
- **[If accurate]** Why do you feel that it's accurate?
 - **[If not accurate]** What seems inaccurate? How could the accuracy be improved?
16. What did you like about this material?
- What did you dislike about this material?
 - What would you change about this material to make it more useful?
17. What do you like or dislike about how the material is designed (i.e., look and feel of the material)?
- What do you like or dislike about how the information is laid out in this material?
 - What do you like or dislike about the colors and graphics used in this material?
 - How easy or difficult is it to scan this material for the most important information?
18. How would you like to receive this material?
- At what point in the **[prescribing / dispensing]** process would you like to receive this material?

PRESCRIBING AND DISPENSING ATTITUDES (3 Minutes)

Finally, I'd like to ask you a few questions about your perceptions of biosimilar products.

Questions

19. After reading the handouts and materials today, how has your impression of biosimilars changed?

Probes

- What do you like about biosimilars based on the materials you just read?
- What do you dislike about biosimilars based on the materials you just read?

20. How comfortable would you be [prescribing / dispensing] biosimilars if they were available in your practice today?

- Why is that?
- What would you still want to know before [prescribing / dispensing] biosimilars to patients?

CLOSING (2 Minutes)

That covers all the questions I wanted to ask today. Is there anything else we should know about biosimilar products that we didn't discuss today?

Observer Questions

[HHS observers will submit any remaining questions to the moderator via text message.]

Closing

Thank you again for participating in today's interview. As I mentioned before, all your comments will remain confidential. Your input has been extremely valuable, and we really appreciate your time.