

FDA Biosimilars Study

Focus Group Moderator Guide

The focus group will comprise the following elements:

- I. **Welcome:**
 - a. **Informed consent**—the interviewer will briefly review the consent form and obtain participants' written consent.
 - b. **Welcome**—the interviewer will thank the participants for taking the time to participate and explain the purpose of the focus group.
 - c. **Warm-Up (Ice Breaker)**—the interviewer will ask participants a few questions about the nature of their work.
- II. **Focus Group Session.** Interactive activities, group discussions and questions to collect participants' knowledge and perceptions.
- III. **Closing.** The interviewer will ask for final thoughts and thank participants for their time.

WELCOME

Welcome (5 mins)

Thank you for coming today. I'm _____, and I'm from RTI International, a nonprofit research organization. The purpose of this focus group is to learn more about your perspective on biological products. Your experience and perspectives are very important to us, and I genuinely appreciate your time today. This session will last about 90 minutes.

I want to let everyone know upfront that I'm not a medical professional, and I am not an expert on the topics we will be discussing. Instead, my role is to moderate today's focus group and ensure that everyone has the chance to express their ideas and opinions.

First, I want to cover two housekeeping items:

1. **Audio and Video Recording.** I want to let everyone know that we're planning to audio and video record 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 recordings when writing the summary.
2. **Client Observation.** I also want to let you know that some other team members are observing this discussion 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 names, addresses, and phone numbers will not be given to anyone, and no one will contact you after this group is over. When I write a summary of these groups, I will not refer to anyone by name.

Second, 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 know what each of you thinks about the issues 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 responses are accurately recorded.
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?

FOCUS GROUP SESSION

Ice Breaker (5 min)

Let's go around the room and introduce ourselves. Please tell me your:

- First name
- Where you grew up
- How long you have been practicing

Understanding of Concepts and Terminology (25 mins)

To get started, I want to ask about your first impressions of some phrases we'll be discussing today. I'll write each phrase on the flip chart, and I'd like you to tell me your first reaction when you see each phrase.

[PRESENT PHRASES ON FLIP CHART, ONE AT A TIME]

<u>Questions</u>	<u>Probes</u>
Phrase: Biological Products	
1. What comes to mind when you hear the phrase "biological products"?	<ul style="list-style-type: none">▪ What specific products come to mind?▪ What conditions/illnesses come to mind?
2. If a patient asked you what a biological product was, what would you say?	<ul style="list-style-type: none">▪ How are these products created?▪ How does a biological product differ from a drug?
3. What biological products have you personally prescribed/dispensed?	
Phrase: Biosimilar Products	
4. What comes to mind when you hear the phrase "biosimilar products"?	
5. How many of you have heard of biosimilar products?	<ul style="list-style-type: none">▪ What have you heard?▪ What developments or news have you heard recently about biosimilar products?

6. If a patient asked you what a biosimilar product was, what would you say?
 - How are biosimilar products similar to original biological products?
 - How are they different from original biological products?
 - What does the phrase “original biological products mean to you?

7. How do biosimilar products compare to generic drugs?
 - What are the similarities?
 - What are the differences?

8. How does the availability of generic drugs affect your [prescribing/dispensing] behavior?
 - What do you think about generic drugs?
 - How often do you [prescribe/dispense] generic drugs instead of brand name drugs?
 - In what cases do you [prescribe/dispense] generics?

9. How would the availability of biosimilar products affect your [prescribing/dispensing] behavior?

Phrase: Reference Products [LOWER PRIORITY]

10. What comes to mind when you hear the phrase “reference products”?

11. If a patient asked you what a reference product was, what would you say?
 - Can you provide an example of a reference product?

Phrase: Interchangeable Biological Products

12. What does the term “interchangeable” mean to you?
- What does it mean for one product to be interchangeable with another?
 - Can you give me an example of two products that are interchangeable?
 - Do you consider generic drugs “interchangeable” with brand name drugs? Why or why not?
 - Do you consider biosimilar products “interchangeable” with other biological products? Why or why not?
13. What is an interchangeable biological product?
- What is the difference between an interchangeable biological product and a biosimilar product?
14. How would the availability of interchangeable biological products affect your [prescribing / dispensing] behavior?

Perceptions of Biosimilar Products (10 mins)

Now I'd like to ask about your general impressions of biosimilar products. By “biosimilar products,” we mean a biological product that is demonstrated to be highly similar to the reference product notwithstanding minor differences in clinically inactive components. And there are no clinically meaningful differences between the biosimilar product and the reference product in terms of safety, purity, and potency.

I want to clarify two pieces of this definition:

- First, when we talk about “reference products,” we're referring to “original biological products.”
- Second, when we talk about “safety, purity, and potency,” we mean “safety and effectiveness.”

Questions

Probes

15. After hearing what we mean by “biosimilar products,” what comes to mind when you hear the term “biosimilar product”?

16. What would you describe as the positive aspects of biosimilar products?
17. What would you describe as the negative aspects of biosimilar products?
18. Overall, do you have a positive or negative impression of biosimilar products?
 - Why is that?

Prescribing and Dispensing Practices (10 mins)

Next, I'd like to find out more about how you currently [prescribe / dispense] biological products to patients.

Questions

19. [Physicians, NPs, PAs only] What factors do you consider when deciding whether to prescribe a specific biological product to patients?
20. [Physicians, NPs, PAs only] Let me give you a scenario...

Imagine a patient comes to you and asks if the original biological product would be better or worse than the biosimilar product.

What would you say to the patient?

21. [Physicians, NPs, PAs only] How comfortable would you be with prescribing biosimilar products?
22. [Pharmacists only] Let me give you a scenario...

Imagine a patient comes to you with a prescription written by their physician for a biosimilar product. The patient asks whether the original biological product would be better or worse than the biosimilar product.

What would you say to the patient?

Probes

- Which factors are most important in your decision?
- Why is that?
- What would make you feel more comfortable with prescribing biosimilar products?
- Why is that?

23. [Pharmacists only] How comfortable would you be with dispensing biosimilar products?
- What would make you feel more comfortable with dispensing biosimilar products?

Knowledge about Biosimilar Product Approval Process (10 mins)

Now I'd like to talk about the approval process for biological, biosimilar, and interchangeable biological products. The Food and Drug Administration (FDA) reviews and approves biological products, including biosimilar and interchangeable biological products.

Questions

24. How familiar are you with FDA's approval process for **biological products** before they are made available to the public?
25. What data or types of studies (e.g., chemistry, manufacturing and controls, animal, human) do you think should be necessary to approve a **biological product**?
26. What data or types of studies (e.g., chemistry, manufacturing and controls, animal, human) do you think should be necessary to approve a **biosimilar product**?
27. What data or type of studies (e.g., chemistry, manufacturing and controls, animal, human) do you think should be necessary to approve an **interchangeable biological product**?

Probes

- Tell me what you know about this process.

Biosimilar Product Definition and Reactions (15 mins)

For our next activity, I'm going to distribute a handout and two highlighters to everyone. I'd like you to take five minutes to read the handout and mark it up using the highlighters. Use the green highlighter to mark elements that you like or find appealing, and use the red highlighter to mark elements that you dislike or find unappealing.

[DISTRIBUTE HANDOUT AND HIGHLIGHTERS. IF PARTICIPANTS ARE UNSURE HOW TO PROCEED, PROVIDE EXAMPLE OF MARKING UP A NEW RESTAURANT MENU USING GREEN AND RED HIGHLIGHTERS.]

Biosimilar Products

A biosimilar is approved through an abbreviated licensure pathway. For an innovator biological product, the goal of development is to demonstrate that the proposed product is safe and efficacious. Approval of the innovator biological product by FDA is based on a full complement of data—such as chemistry data, animal studies, and phase 1, 2, and 3 human studies. For the proposed biosimilar product, the goal of product development is to demonstrate biosimilarity between the proposed product and an FDA-licensed biological product (the reference product), not to independently establish safety and effectiveness. Therefore, a proposed biological product that is demonstrated to be “highly similar” to the reference product may rely on certain existing scientific knowledge about the safety, purity, and potency (i.e., effectiveness) of the reference product. This licensure pathway permits a “biosimilar” biological product to be licensed based on less than a full complement of product-specific nonclinical and clinical data. This is how a biosimilar can get to the public faster and likely at a reduced cost.

A biosimilar product is a biological product that is demonstrated to be “highly similar” to the reference product notwithstanding minor differences in clinically inactive components. In addition, there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency (i.e., effectiveness) of the product.

Reference Products

A reference product is the single biological product, licensed under section 351(a) of the Public Health Services Act (the PHS Act), against which a biological product is evaluated in an application submitted under section 351(k) of the PHS Act. (What this means is the following: to develop a biosimilar, which is being developed through an abbreviated licensure pathway described in section 351(k) of the statute, the manufacturer needs to compare the proposed biosimilar to an innovator biological product that was previously approved by FDA on a full complement of data. The innovator biological product is the “single biological product licensed under section 351(a) of the PHS Act.”)

Interchangeable Biological Products

To meet the additional standard of “interchangeability,” an applicant must provide sufficient information to demonstrate biosimilarity, and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. Interchangeable biological products may be substituted for the reference product without the intervention of the prescribing healthcare provider.

Let's look at our handouts...

Questions

28. What parts did you highlight in green?

Probes

- What did you like about these elements?

29. What parts did you highlight in red?

- What did you dislike about these elements?

30. Based on this information, how has your overall impression of biosimilar products changed?

31. How has your overall impression of interchangeable biological products changed?

32. [Physicians, NPs, PAs only] After reading this definition, are you more or less comfortable with the idea of prescribing a biosimilar product?

- Why is that?
- What in the definition changed your opinion?

33. [Physicians, NPs, PAs only] Let me give you another scenario...

You previously prescribed a biological product for a patient, and a new biosimilar product has become available.

How comfortable would you be prescribing the biosimilar product at the patient's next visit?

34. [Physicians, NPs, PAs only] Let me give you another scenario...

You previously prescribed a biological product for a patient, and a new interchangeable biological product has become available.

How comfortable would you be prescribing the interchangeable biological product at the patient's next visit?

35. [Pharmacists only] After reading this definition, are you more or less comfortable with the idea of dispensing a biosimilar product?

- Why is that?
- What in the definition changed your opinion?

36. [Pharmacists only] Let me give you a scenario...

A patient comes to you with a prescription from their physician for a new biosimilar product now available.

How comfortable would you be dispensing the biosimilar product instead of the original biological product?

37. [Pharmacists only] Let me give you another scenario...

A patient comes to you with a prescription from their physician for a biological product, and a new interchangeable biological product is now available.

How comfortable would you be dispensing the interchangeable biological product instead of the original biological product?

Biological Product Information Sources (10 mins)

Finally, I'd like to know more about which sources of information you use to learn about new medical products.

Questions

38. What is your primary source of information for biological products?
39. What other sources are available for you to find information about biological products?

Probes

[Probe based on the response. For example, if the response is "online," a probe may be which sites do you go to? Why do you go to those sites?]

- Where would you go to find information about biosimilar products?
- Where would you go to find information about interchangeable biological products?
- What sources are you aware of that you currently do not use?

40. If a new biological product were approved, how would you first learn about it?
- Where would you go to find more information about it?
 - Why would you go there?
41. What information is important for healthcare providers to know about biosimilar products?
- What information would you want to know about a biosimilar product prior to [prescribing/dispensing] it?
42. How would you like to receive or find information about biosimilar products?
- What is the best way to share information about new products with busy healthcare providers?

III. CLOSING

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 session. As I mentioned before, all your comments will remain confidential. Your input has been extremely valuable, and we really appreciate your time.