

Biosimilars Patient Study

Focus Group Moderator Guide

WELCOME (5 MINUTES)

Welcome, everyone, and thank you for participating in our discussion today. My name is _____, and I work for RTI International, a nonprofit research organization. We are conducting this study on behalf of the U.S. Food and Drug Administration, or FDA. The FDA would like your feedback on some informational materials about biologic medicines. Our discussion will help FDA identify where improvements to the materials might be needed, so your feedback is very important. Our session will last about 90 minutes.

I want to let everyone know that I'm not a medical professional or an expert on the topics we will discuss. My role is simply to moderate the group and ensure that everyone has the chance to express their ideas and opinions.

Before we begin the discussion, I want to review a few highlights from the consent form you were sent via email:

- **Participation.** First, your participation is voluntary. You don't have to answer any questions you don't want to answer. Also, at any point you may stop participating.
- **Recording.** We are audio and video recording today's session so that I can give you my full attention and not take a lot of notes. Please speak clearly and loudly enough for everyone to hear. Also, please minimize background noise by finding a quiet location away from other people and distractions.
- **Observers.** We also have some members of the research team, including from the FDA, watching tonight's discussion so they can hear your opinions directly from you.
- **Privacy.** We will keep your identity secure to the extent permitted by law. Only the Survey Healthcare recruiters and FocusVision staff have your full name and contact information, and they will not share that information with anyone. I ask that you use only first names today when referring to yourself or others, and please do not share information about today's discussion outside of this group.

I also want to highlight a few ground rules for today's discussion:

- **Timing.** I have a discussion guide in front of me to help us stay on track. We have a lot of topics to cover, so I may have to break off the conversation at times so that we can move on to the next topic.
- **Speak One at a Time.** I'm interested in hearing opinions from all of you, so you don't have to wait for me to call on you to join the conversation. Please just speak one at a time. I may occasionally interrupt you to make sure everyone gets a chance to speak and that responses are accurately recorded.
- **Cell Phones.** If you haven't already, please silence your cell phones and other devices.
- **Technical Assistance.** If you need technical assistance at any point, please use the chat function on the right side of your screen to ask our technical support representative, _____, for help.
- **Honest Opinions.** Most importantly, there are no right or wrong answers. I just want your honest opinions about the materials we'll be reviewing today. I did not create the materials you will see today, so please feel free to be honest and direct in your answers; you're not going to hurt my feelings.

Does anyone have any questions before we begin?

WARM UP (5 MINUTES)

I'd like to begin the discussion by going around and introducing ourselves. Please tell us:

- Your first name
- Which state you are joining us from
- Complete this sentence: "I believe I am in good health when..."

[CALL ON SPECIFIC PARTICIPANTS TO SHARE, ONE BY ONE.]

BIOSIMILAR AWARENESS AND INFORMATION NEEDS (10 MINUTES)

First, I'd like to talk about your thoughts and experiences with biologic medicines, or biologics, which you all mentioned you are currently or have recently taken.

To make sure we're all on the same page, I want to review FDA's definition of a biologic. [Read]

Biologic products (also called biologics) are medicines made from natural and living sources--such as animals, plants, or yeast—and are produced through biotechnology in a living system.

[DIABETES GROUPS] Short- and long-acting insulins, such as Humulin, Novolin, and Insuman, are common biologics used to treat diabetes. I'd like to focus our discussion today on your experiences and thoughts about the biologics [you/your child] have taken, rather than [your experiences/your child's experiences] with diabetes itself. However, please feel free to share any information you think provides important context for your responses.

[ALL OTHER GROUPS] Common biologics used to treat [CONDITION] include [list a few biologics mentioned in participants' screener responses]. I'd like to focus our discussion today on your experiences and thoughts about the biologics you have taken, rather than your experiences with [CONDITION] itself. However, please feel free to share any information you think provides important context for your responses.

<u>Questions</u>	<u>Probes</u>
1. Biologic Familiarity. In your own words, how are biologics different from other types of medicine?	

Now I want to talk about biosimilar products.

<u>Questions</u>	<u>Probes</u>
2. Biosimilar Familiarity. How many of you have heard of biosimilar medicines?	<ul style="list-style-type: none">▪ What have you heard about them?▪ In your own words, what are biosimilars?
3. Biosimilar Experience. [SKIP FOR DIABETES GROUPS] How many of you have previously taken or are currently taking a biosimilar?	<ul style="list-style-type: none">▪ What did your doctor, pharmacist, or another healthcare professional tell you about biosimilars?▪ For those who haven't taken a biosimilar, have you talked about biosimilars with your healthcare professional? Tell me about that

	conversation.
4. Biosimilar Information Needs. What do you still want to know about biosimilars that your healthcare professional hasn't already explained?	<ul style="list-style-type: none"> ▪ What level of detail would you prefer for this information? ▪ In what format would you prefer to receive information about biosimilars? For example, a physical handout or pamphlet, website, video?

MATERIALS TESTING (55 MINUTES)

Now I want to show you some materials FDA developed about biosimilar products. We're going to look at three different types of materials, one at a time. I'll share each of the materials on my screen, give you time to review it, and then we'll discuss each material as a group. Let's get started with the discussion.

[ROTATE PRESENTATION ORDER OF WRITTEN MATERIALS VS. VIDEOS, AS DEPICTED IN DESIGN GRAPHIC]

INFOGRAPHIC (15 MINUTES)

[DISPLAY INFOGRAPHIC. LET PARTICIPANTS REVIEW IT FOR 2 MINUTES.]

The material I'm showing you now is an infographic. Please take a few minutes to read this and then I'll ask you some questions about it. I'll keep the infographic on the screen for your reference.

<u>Questions</u>	<u>Probes</u>
5. First Impressions. What are your first thoughts after seeing this infographic?	<ul style="list-style-type: none"> ▪ What do you like about it? Why? ▪ What do you dislike about it? Why?
6. Main Message. In your own words, what are the main messages in this infographic?	<ul style="list-style-type: none"> ▪ How well does the title "Biosimilar Basics" describe the information contained in the infographic? ▪ What is this infographic asking you to do?
7. Comprehension. How easy or difficult is it to understand the information in the infographic?	<p>[ASK ALL PROBES]</p> <ul style="list-style-type: none"> ▪ What words or phrases are confusing or hard to understand? ▪ Based on this information, how is a biosimilar related to an original biologic? ▪ What are some reasons for using a biosimilar instead of the original biologic? ▪ [If needed] What about reasons besides lower cost? ▪ Based on this information, what is FDA's role once a biosimilar medication is approved?
8. Missing Information. Keeping in mind this infographic will be read by patients with various medical conditions, what additional information do you think should be added?	<ul style="list-style-type: none"> ▪ Where would you add this information?

<p>9. Trust. How much do you trust this infographic?</p>	<ul style="list-style-type: none"> ▪ Why is that? ▪ What would make the infographic more trustworthy?
<p>10. Usefulness. How useful is this infographic for you personally?</p>	<ul style="list-style-type: none"> ▪ Why is it useful? ▪ Why is it not useful? ▪ Which of the five horizontal sections did you find most useful? Why? ▪ Which of the sections did you find least useful? Why?
<p>11. Visual Design. How do you feel about the way the infographic looks?</p>	<ul style="list-style-type: none"> ▪ What do you like about the visuals? ▪ What do you dislike about them? ▪ How well do the images go with this information? ▪ What do you think about the way the information is organized in the infographic and how it flows? ▪ What would you change about the visuals in this infographic?
<p>12. Preferred Channels. Where would you like to see this infographic?</p>	<ul style="list-style-type: none"> ▪ Where would the infographic need to be for <u>you</u> to pay attention to it? <ul style="list-style-type: none"> ○ [If not mentioned] Doctor's office? Pharmacy? Certain websites? Social media?
<p>13. Behavioral Intentions. How do you feel about biosimilars after reading this infographic?</p>	<ul style="list-style-type: none"> ▪ How would this infographic affect your willingness to try a biosimilar? ▪ After seeing this infographic, how comfortable would you be discussing biosimilars with your healthcare professional?
<p>14. Recommendations. What other changes would you suggest to make this infographic more useful?</p>	

FACT SHEET (15 MINUTES)

The material I'm showing you now is a fact sheet. While you review the fact sheet, I'd like you to keep in mind specific sentences or phrases you like and sentences or phrases you dislike.

[DISPLAY FACT SHEET. LET PARTICIPANTS REVIEW THE FACT SHEET FOR 4 MINUTES.]

Let's get started with the discussion. If you haven't quite finished reading, you can finish up while we talk.

<u>Questions</u>	<u>Probes</u>
<p>15. First Impressions. What are your first thoughts after seeing this fact sheet?</p>	<ul style="list-style-type: none"> ▪ What do you like about it? Why? ▪ What do you dislike about it? Why?
<p>16. Main Message. In your own words, what are the main messages in this fact sheet?</p>	<ul style="list-style-type: none"> ▪ How well does the title “4 Facts about Biosimilars” describe the information contained in the fact sheet? ▪ If there were one thing that you could take from the fact sheet and add to the infographic you saw earlier, what would that be?
<p>17. Comprehension. How easy or difficult is it to understand the information in the fact sheet?</p>	<p>[ASK ALL PROBES]</p> <ul style="list-style-type: none"> ▪ What words or phrases are confusing or hard to understand? ▪ The second section mentions “natural differences.” What does that mean to you? Is it helpful information? ▪ Based on this information, how are interchangeables related to biosimilars?
<p>18. Missing Information. Keeping in mind this fact sheet will be read by patients with various medical conditions, what additional information do you think should be added?</p>	<ul style="list-style-type: none"> ▪ Where would you add this information?
<p>19. Trust. How much do you trust the fact sheet?</p>	<ul style="list-style-type: none"> ▪ Why is that? ▪ What would make the fact sheet more trustworthy?
<p>20. Usefulness. How useful is this fact sheet for you personally?</p>	<ul style="list-style-type: none"> ▪ Why is it useful? ▪ Why is it not useful? ▪ Which of the four sections/facts did you find most useful? Why? ▪ Which of the four sections/facts did you find least useful? Why?
<p>21. Visual Design. How do you feel about the way the fact sheet looks?</p>	<ul style="list-style-type: none"> ▪ What do you like about the visuals? ▪ What do you dislike about them? ▪ What do you think about the way the information is organized in the fact sheet and how it flows? ▪ What would you change about the way this fact sheet looks?
<p>22. Preferred Channels. Where would you like to see this fact sheet?</p>	<ul style="list-style-type: none"> ▪ Where would the fact sheet need to be for <u>you</u> to pay attention to it (e.g. read it)? <ul style="list-style-type: none"> ○ [If not mentioned] Doctor's office?

	Pharmacy? Certain websites? Social media?
23. Behavioral Intentions. How do you feel about biosimilars after reading this fact sheet?	<ul style="list-style-type: none"> ▪ How would this information affect your willingness to try a biosimilar? Why is that? ▪ After seeing this fact sheet, how comfortable would you be discussing biosimilars with your healthcare professional?
24. Recommendations. What other changes would you suggest to make this fact sheet more useful?	

VIDEOS (25 MINUTES)

I'm going to show you a series of four videos, one at a time. We'll pause after each video for a brief discussion.

[SHOW VIDEOS 1-4, PAUSING AFTER EACH TO ANSWER Q25-29. ASK Q30-35 AFTER WATCHING ALL FOUR VIDEOS.]

<u>Questions</u>	<u>Probes</u>
Ask after each video	
25. First Impressions. What are your first thoughts after seeing this video?	<ul style="list-style-type: none"> ▪ What did you like about it? Why? ▪ What did you dislike about it? Why?
26. Main Message. In your own words, what are the main messages in this video?	
27. Comprehension. How easy or difficult is it to understand the information in the video?	<p>[ASK ALL PROBES]</p> <ul style="list-style-type: none"> ▪ [If not mentioned] What words or phrases in the video are confusing or hard to understand? What words or phrases would be easier to understand? ▪ Video 1. Based on the video, why would a patient be prescribed a biosimilar, including patients who may already be taking a biologic? ▪ Video 2. What are the key facts to know about biosimilars? Does the comparison to generics help you understand biosimilars? ▪ Video 3. How do biosimilars compare to the original biologic? ▪ Video 4. How does FDA determine that biosimilars are safe and effective?
28. Usefulness. How useful is this video for you personally?	<ul style="list-style-type: none"> ▪ Why is it useful? ▪ Why is it not useful?
29. Missing Information. Keeping in mind this video will be seen by patients with various	<ul style="list-style-type: none"> ▪ Where would you add this information?

<p>medical conditions, what additional information do you think should be added?</p>	
<p>Ask after watching all 4 videos [DISPLAY PDF OF VIDEO TITLE SCREENS]</p>	
<p>30. Trust. How much do you trust the videos?</p>	<ul style="list-style-type: none"> ▪ Why is that? ▪ What would make the videos more trustworthy? ▪ Do these conversations between a patient or doctor seem realistic to you? Why?
<p>31. Usefulness. Which video did you find most useful? Why?</p>	<ul style="list-style-type: none"> ▪ Which video did you find least useful? Why?
<p>32. Visual Design. How do you feel about the way the videos look?</p>	<ul style="list-style-type: none"> ▪ What do you think about the cartoon characters used? ▪ How do you feel about this information being shown to you using cartoon characters? ▪ What would you change about the way these videos look if you could?
<p>33. Preferred Channels. Where would you expect to see these videos?</p>	<ul style="list-style-type: none"> ▪ Where would the videos need to be for <u>you</u> to pay attention to them? <ul style="list-style-type: none"> ○ [If not mentioned] Doctor's office? Pharmacy? Certain websites? Social media?
<p>34. Behavioral Intentions. How do you feel about biosimilars after viewing these videos?</p>	<ul style="list-style-type: none"> ▪ How would these videos affect your willingness to try a biosimilar? ▪ After seeing this fact sheet, how comfortable would you be discussing biosimilars with your healthcare professional?
<p>35. Recommendations. What other changes would you suggest to make these videos more useful?</p>	<ul style="list-style-type: none"> ▪ Do you think the videos should be viewed as a set, or could some be watched individually? Why is that? <ul style="list-style-type: none"> ○ [If needed] Do you like short videos like this that break up the content, or would you prefer one longer video that covers everything? Why? ▪ In which order would you prefer to view the videos? Why?

MATERIALS REFLECTION (13 MINUTES)

Now that you've seen all the videos, fact sheet, and infographic, I have a few final questions about the materials overall.

<u>Questions</u>	<u>Probes</u>
36. Interpretation. After seeing the materials, how would you describe “biosimilars”?	<ul style="list-style-type: none"> ▪ What is the difference between a biosimilar and the original biologic, in your own words?
37. Relevance. For whom do you think these materials are intended?	<ul style="list-style-type: none"> ▪ To what extent do you feel like these materials were made for someone with a condition like yours? ▪ What would make the materials more relevant for you or others with the same condition?
38. Usefulness. How helpful are these materials at informing you about biosimilars?	<ul style="list-style-type: none"> ▪ Which of these materials would be most helpful in preparing to talk to your healthcare professional about biosimilars?
39. Role of FDA. Why do you think FDA developed these materials about biosimilars?	<ul style="list-style-type: none"> ▪ How likely are you to visit the FDA website to learn more about biosimilars? ▪ How trustworthy is FDA as a source for information about biosimilars? Why is that? ▪ Do you consider any sources of information about biosimilars to be more trustworthy than FDA? Which ones, and why?
40. Information Gaps. What questions do you still have about biosimilars after seeing these materials?	<ul style="list-style-type: none"> ▪ What other questions might people have about the <u>approval process</u> for biosimilars that aren't addressed in the materials? ▪ What other questions might people have about the <u>safety</u> of biosimilars that aren't addressed in the materials? ▪ What else would you need to know after seeing the materials to make an informed decision about using a biosimilar?

CLOSING (2 MINUTES)

Your feedback has been very helpful. **[CHECK CHAT BOX FOR ANY CLARIFYING QUESTIONS FROM OBSERVERS.]**

Thank you again for participating in today's session. Specific instructions for obtaining your \$75 honorarium will be sent to you by email at the conclusion of the research.