

Biosimilars Patient Study *Interview Guide (Phase 2)*

The 90-minute interview will comprise the following elements:

I. Welcome / Warm Up (4 mins):

- a. Welcome—The interviewer will thank the participant for taking the time to participate. He/she will then explain the purpose of the interview, review highlights of the consent form, discuss ground rules, and answer any remaining questions before the interview begins.
- b. Warm-Up—The interviewer will ask the participant to introduce themselves, including which medicine(s) they take most often to treat their condition.

II. Biosimilar Awareness and Information Needs (5 mins):

- a. Familiarity and Experience—To what extent is the participant aware of biologics and biosimilars? Have they ever taken or are they currently taking a biosimilar?
- b. Information Needs—What are the information needs and priorities of participants related to biologics?

III. Materials Testing - Infographic, Fact Sheet, Video Animatic (65 mins, 20-25 per material):

- a. First Impressions - What initial thoughts does the participant have about the material?
- b. Main Message - What does the participant see as the main message(s) in the material?
- c. Comprehension—How well does the participant understand the information in the material?
- d. Usefulness—To what extent does the participant perceive the materials as useful and relevant to their health and treatment decisions?
- e. Visual Design—How does the participant respond to the visual design of the material (e.g., graphics, layout, depiction of medical condition, flow of information)?
- f. Behavioral Intentions - How prepared does the participant feel to talk with a healthcare professional about biosimilars after reviewing the material?

IV. Materials Reflection (After Viewing All Materials) (15 mins):

- a. Usefulness—Which material does the participant find most useful for making treatment decisions?
- b. Relevance—To what extent does the participant think the materials were developed for them?
- c. Trust - How trustworthy is FDA as a source of information about biosimilars?
- d. Call to Action - What steps would the participant take to learn more about biosimilars?
- e. Information Gaps—What questions about biosimilars does the participant still have after seeing the materials?
- f. Recommendations - What additional changes to the materials does the participant recommend?

- V. Closing (1 min).** The moderator will ask for final thoughts and thank the participant for their time.

Priority Question Coding

High = Ask in every interview

Average = Ask if not already mentioned

Low = Ask only if not already mentioned and time permits

WELCOME (3 MINUTES)

Welcome and thank you for participating 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 discussion will last about 90 minutes.

I want to let you know that I'm not a medical professional or an expert on the topics we will discuss. My role is simply to moderate our discussion and ensure that you have the chance to express your ideas and opinions.

Before we begin, 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 our discussion so that I can give you my full attention and not take a lot of notes. Please speak clearly and loudly. Also, please minimize background noise by finding a quiet location away from other people and distractions. If you haven't already, please silence your cell phone and other devices.
- **Observers.** We also have some members of the research team, including from the FDA, watching our 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 L&E recruiters have your full name and contact information, and they will not share that information with anyone. I ask that you use only your first name during today's interview.

I also want to highlight a few ground rules for our 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 move us on to the next topic if we're running short on time.
- **Technical Assistance.** If you need technical assistance at any point, just let me know and we can try to resolve it.
- **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.

Do you have any questions before we begin?

WARM UP (1 MINUTE)

You were recruited for this study because you have [CONDITION] and are taking at least one medicine to treat it. I'd like to begin by having you introduce yourself. Please share:

- The state in which you live
- Which medicine [do you take/does your child take] most often to treat [CONDITION]?

BIOSIMILAR AWARENESS AND INFORMATION NEEDS (5 MINUTES)

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

Because not all patients and caregivers are familiar with the term, 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 animal cells or yeast.

[DIABETES PATIENTS/CAREGIVERS] 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/has 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 PARTICIPANTS] Common biologics used to treat [\[CONDITION\]](#) include [\[list any biologics mentioned in the participant's screener responses; if participant mentioned only one biologic, mention a few others available for participant's condition\]](#). 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.

Now I want to talk about biosimilar products.

<u>Questions</u>	<u>Probes</u>
<p>1. Biosimilar Familiarity. Had you heard of biosimilar medicines before today?</p>	<ul style="list-style-type: none"> ▪ [IF YES] What have you heard about them? ▪ [IF YES] Where did you receive your information about biosimilars? ▪ [FOR DIABETES PATIENTS/CAREGIVERS] What have you heard about a biosimilar form of insulin becoming available?
<p>2. Biosimilar Experience. [SKIP FOR DIABETES PATIENTS/CAREGIVERS] Have you previously taken or are you currently taking a biosimilar?</p>	<ul style="list-style-type: none"> ▪ [IF YES] What has been your experience with taking a biosimilar? ▪ [IF NO, BUT SCREENER RESPONSE INDICATES BIOSIMILAR USE] Maybe you aren't aware, but [MEDICINE]—which you mentioned taking—is actually a biosimilar. What has been your experience with taking that medicine?
<p>3. Biosimilar Information Needs. [FOR GENERAL PATIENTS] What do you still want to know about</p>	

<p>biosimilars?</p> <p>[FOR DIABETES PATIENTS/CAREGIVERS] What do you still want to know about biosimilar forms of insulin?</p>	
---	--

MATERIALS TESTING (65 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 one. Let’s get started.

[ROTATE PRESENTATION ORDER OF WRITTEN MATERIALS VS. VIDEO ANAMATIC, AS DEPICTED IN TESTING ORDER DOCUMENT]

INFOGRAPHIC (20 MINUTES)

[DISPLAY INFOGRAPHIC.]

The material I’m showing you now is an infographic that healthcare professionals or others might share with patients. 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.

[LET PARTICIPANT REVIEW IT FOR 2 MINUTES.]

Questions	Probes
<p>4. First Impressions. What are your first reactions after reading this infographic?</p>	<ul style="list-style-type: none"> ▪ Why did you have that reaction? ▪ What do you like about it? Why? ▪ What do you dislike about it? Why?
<p>5. Main Message. In your own words, what are the main messages in this infographic?</p>	

[IF PARTICIPANT HAS ALREADY REVIEWED VIDEO, PREFACE COMPREHENSION QUESTIONS BY ASKING HOW INFOGRAPHIC HAS CHANGED THEIR UNDERSTANDING OF THIS INFORMATION]

<p>6. Comprehension – Product Attributes. Based on this information, how is a biosimilar related to an original biologic?</p>	<ul style="list-style-type: none"> ▪ In your own words, how is a biosimilar <u>like</u> an original biologic? ▪ How is a biosimilar <u>different</u> from an original biologic? ▪ How do the side effects of a biosimilar compare with the side effects of an original biologic? ▪ How do the benefits of a biosimilar compare with the benefits of an original biologic? ▪ In your own words, how is a biosimilar <u>like</u> a generic drug? ▪ How is a biosimilar <u>different</u> from a generic
--	--

	drug?
7. Comprehension – Sources and Ingredients. What types of sources or ingredients are used to make biosimilars?	<ul style="list-style-type: none"> What does the infographic mean when it says that biosimilars are made from “living sources?”
8. Comprehension – Reasons for Using. Based on the infographic, what are some reasons for using a biosimilar instead of an original biologic?	<ul style="list-style-type: none"> How do you feel about biosimilars costing less than original biologics? What concerns do you have about biosimilars costing less than original biologics?
9. Comprehension – Points of Confusion. What information in the infographic needs more explanation?	<ul style="list-style-type: none"> What do you think other people might find confusing in this infographic? How would you change the information in this infographic to make it easier to understand?
10. Usefulness. How useful is this infographic for you personally? Why?	<ul style="list-style-type: none"> What information in the infographic is most useful to you? Why?
11. Visual Design. What would you change about the way this infographic looks?	<ul style="list-style-type: none"> What do you think about the way the information is organized and how it flows?
12. Behavioral Intentions. Does seeing this infographic make you feel more prepared or less prepared to discuss biosimilars with your healthcare professional?	<ul style="list-style-type: none"> Why is that? What could be changed in the infographic to help you feel more prepared for that conversation?

FACT SHEET (20 MINUTES)

The material I’m showing you now is a fact sheet. Healthcare professionals or others might share this fact sheet with patients like you. The fact sheet is 3 pages and I will scroll through it for you. As you read, let me know when you’re ready for me to move to the next page.

[DISPLAY FIRST PAGE OF FACT SHEET. LET PARTICIPANT REVIEW THE ENTIRE FACT SHEET FOR 5 MINUTES. SCROLL WHEN APPROPRIATE.]

Questions	Probes
13. First Impressions. What are your first reactions after reading this fact sheet?	<ul style="list-style-type: none"> Why did you have that reaction? What do you like about it? Why? What do you dislike about it? Why?
14. Main Message. In your own words, what are the main messages in this fact sheet?	<ul style="list-style-type: none"> [FOR DIABETES PATIENTS/CAREGIVERS] The fact sheet states that insulin is now being regulated as a biologic. What does that mean for [you / your child]?
15. Comprehension – Minor Differences in Batches. In what way are biosimilars similar but not identical to original biologics?	<ul style="list-style-type: none"> How do you feel about the fact that biosimilars can have minor differences between batches? Why did the fact sheet compare biosimilars to

	<p>[oranges/loaves of bread]?</p> <ul style="list-style-type: none"> Now I'd like to show you a slightly different version of the fact sheet. [Display alternate analogy.] Why did the fact sheet compare biosimilars to [oranges/loaves of bread]? Which of these two comparisons—oranges or bread—did you find most helpful? Why?
<p>16. Comprehension – FDA Oversight. Based on the fact sheet, when and how does FDA ensure biosimilars are safe and effective?</p>	<ul style="list-style-type: none"> What else would you like to know about FDA's oversight of biosimilars that isn't mentioned in the fact sheet?
<p>17. [Ask only if participant was uncertain or unclear about these attributes when reviewing the infographic]</p> <p>Comprehension – Product Attributes. Based on this information, how is a biosimilar related to an original biologic?</p>	<ul style="list-style-type: none"> In your own words, how is a biosimilar <u>like</u> an original biologic? How is a biosimilar <u>different</u> from an original biologic? In your own words, how is a biosimilar <u>like</u> a generic drug? How is a biosimilar <u>different</u> from a generic drug?
<p>18. [Ask only if participant was uncertain or unclear about these attributes when reviewing the infographic]</p> <p>Comprehension – Reasons for Using. Based on the fact sheet, what are some reasons for using a biosimilar instead of an original biologic?</p>	<ul style="list-style-type: none"> How do you feel about biosimilars costing less than original biologics? What concerns do you have about biosimilars costing less than original biologics?
<p>19. Comprehension – Points of Confusion. What information in the fact sheet needs more explanation?</p>	<ul style="list-style-type: none"> What do you think other people might find confusing in this fact sheet? How would you change the information in this fact sheet to make it easier to understand? If there were one thing you could take from the fact sheet and add to the infographic you saw earlier, what would that be?
<p>20. Usefulness. How useful is this fact sheet for you personally? Why?</p>	<ul style="list-style-type: none"> What information in the fact sheet is most useful to you? Why?
<p>21. Visual Design. What would you change about the way this fact sheet looks?</p>	<ul style="list-style-type: none"> What do you think about the way the information is organized and how it flows?
<p>22. Behavioral Intentions. Does seeing this fact sheet make you feel more prepared or less prepared to discuss biosimilars with your healthcare professional?</p>	<ul style="list-style-type: none"> Why is that? What could be changed in the fact sheet to help you feel more prepared for that conversation?

VIDEO (25 MINUTES)

I'm going to show you an early draft of what will eventually be a short, animated video about biosimilars. A fully animated version has not been created yet, so we're going to watch a string of images edited together with sound to show you how the video will flow. Once finalized, you might see the video shared on social media by the FDA or patient advocacy organizations or featured on their websites. Please keep this in mind for our discussion.

[PLAY THE VIDEO]

Questions	Probes
<p>23. First Impressions. What are your first reactions after watching the video?</p>	<ul style="list-style-type: none"> ▪ Why did you have that reaction? ▪ What do you like about it? Why? ▪ What do you dislike about it? Why?
<p>24. Main Message. In your own words, what are the main messages in this video?</p>	
<p>[IF PARTICIPANT HAS ALREADY REVIEWED INFOGRAPHIC AND FACT SHEET, PREFACE COMPREHENSION QUESTIONS BY ASKING HOW VIDEO HAS CHANGED THEIR UNDERSTANDING OF THIS INFORMATION]</p>	
<p>25. Comprehension – Product Attributes. Based on this video, how is a biosimilar related to an original biologic?</p>	<ul style="list-style-type: none"> ▪ In your own words, how is a biosimilar <u>like</u> an original biologic? ▪ How is a biosimilar <u>different</u> from an original biologic? ▪ How do the side effects of a biosimilar compare with the side effects of an original biologic? ▪ How do the benefits of a biosimilar compare with the benefits of an original biologic? ▪ In your own words, how is a biosimilar <u>like</u> a generic drug? ▪ How is a biosimilar <u>different</u> from a generic drug?
<p>26. Comprehension – Sources and Ingredients. What types of sources or ingredients are used to make biosimilars?</p>	<ul style="list-style-type: none"> ▪ What does the video mean when it says that biosimilars are made from “living sources?”
<p>27. Comprehension – Reasons for Using. Based on the video, what are some reasons for using a biosimilar instead of an original biologic?</p>	<ul style="list-style-type: none"> ▪ How do you feel about biosimilars costing less than original biologics? ▪ What concerns do you have about biosimilars costing less than original biologics?
<p>28. Comprehension – Points of Confusion. What information in the video needs more explanation?</p>	<ul style="list-style-type: none"> ▪ What do you think other people might find confusing in this video?

	<ul style="list-style-type: none"> How would you change the information in this video to make it easier to understand?
<p>29. Usefulness. How useful is this video for you personally? Why?</p>	<ul style="list-style-type: none"> What information in the video is most useful to you? Why?
<p>30. Visual Design. Keeping in mind that this video included draft images, what would you change about the way the final video looks? Why?</p>	<ul style="list-style-type: none"> The video depicts a patient in a doctor's office. How helpful are these images in delivering the information about biosimilars? Why is that? Does the video treat the topics of biosimilars and [CONDITION] respectfully?
<p>31. Behavioral Intentions. Does seeing this video make you feel more prepared or less prepared to discuss biosimilars with your healthcare professional?</p>	<ul style="list-style-type: none"> Why is that? What could be changed in the video to help you feel more prepared for that conversation?

MATERIALS REFLECTION (15 MINUTES)

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

Questions	Probes
<p>32. Usefulness. Which of these materials would be most helpful in preparing to discuss biosimilars with your healthcare professional?</p>	<ul style="list-style-type: none"> Why would that material be most helpful?
<p>33. Relevance. To what extent do you feel like these materials were made for someone with [your / your child's] health condition?</p>	<ul style="list-style-type: none"> What would make the materials more relevant for you or others with the same condition? What types of health conditions can be treated by biosimilars?
<p>34. Trust. How trustworthy is FDA as a source of information about biosimilars?</p>	<ul style="list-style-type: none"> Why do you say that?
<p>35. Call to Action. In your own words, what are these materials asking you to do?</p>	<ul style="list-style-type: none"> Where would you go if you wanted to learn more about biosimilars in general? Where would you go if you wanted to learn about the benefits and side effects of specific biosimilars that treat [your / your child's] health condition?
<p>36. Information Gaps. What questions do you still have about biosimilars after seeing these materials?</p>	<ul style="list-style-type: none"> What questions might people have about the approval process for biosimilars that aren't addressed in the materials? What questions might people have about the safety of biosimilars that aren't addressed in the materials?

	<ul style="list-style-type: none">▪ What else would you need to know after seeing the materials to make an informed decision about using a biosimilar?
37. Recommendations. What other changes would you suggest to make these materials more useful?	

CLOSING (1 MINUTE)

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

Thank you again for participating in our discussion. Specific instructions for obtaining your \$75 honorarium will be sent to you by email within one business day.