



Studies to Enhance Food and Drug Administration (FDA) Communications Addressing Biosimilar Drug Products—Patient Focus Groups

SEMI-STRUCTURED MODERATOR'S GUIDE



Research Objective: Conduct 10 focus groups, each with between six and ten consumers who currently take or have recently taken biologics or biosimilars (within the last six months) to obtain insight into and feedback about patients' knowledge, experiences, and opinions related to these products. The findings from these groups will be used to help inform the Center for Drug Evaluation and Research's (CDER) communications about specific biological products demonstrated to be "biosimilar" to or "interchangeable" with a Food and Drug Administration (FDA)-approved biologic product. Patients who have used biologics are the most likely to have already been prescribed biosimilars, or to be prescribed biosimilars or interchangeable biologics in the future, and are thus the target audience for these communications. FDA has approved 18 biosimilars to date, but less than half are currently on the market; therefore, patients' knowledge, experience with, and opinions about these specific biologic products is expected to be limited.

SESSION OVERVIEW: Total time 90 minutes

SECTION 1: Introduction and Warm-Up (5 mins.)

The moderator will explain the purpose of the research, present the ground rules, allow the participants to ask any questions, and get to know the participants.

SECTION 2: Knowledge of Biologics (7 mins.)

The purpose of this section is to establish patients' baseline understanding and knowledge about biologics.

SECTION 3: Thoughts, Experiences, and Desired Information Related to Biologics (30 mins.)

The purpose of this section is to understand patients' thoughts, attitudes, and experiences with using biologics. This section also explores what information patients have received about biologics and what information they would like to have.

SECTION 4: Knowledge, Thoughts, Experiences, and Desired Information Related to Biosimilars (25 mins.)

The purpose of this section is to understand patients' knowledge, thoughts, attitudes, and experiences with using biosimilars. This section also explores what information patients have received about biosimilars and what information they would like to have.

SECTION 5: Biosimilar and Interchangeable Product Educational Materials (15-18 mins.)

The purpose of this section is to gather reactions to the educational materials FDA developed for patients related to biosimilar products. One group from each medical condition segment will be asked to provide feedback on either an infographic or two public service announcements (PSAs).

SECTION 6: Conclusion (5 mins.)

The moderator wraps up the discussion and ensures that all questions have been answered and all comments have been heard. The moderator will employ a false close in which FDA and/or FMG research team members can

communicate with FMG support if there are specific topics for the moderator to follow up on with participants.

Section 1: Introduction and Warm-Up (5 minutes)

Thank you for taking the time to talk with me. My name is [Moderator name], and I'll be leading our group discussion today. I work for an independent research company, Fors Marsh Group, which is conducting a study for the Food and Drug Administration, or FDA. The FDA wants to hear your thoughts and experiences related to biological products, which are a type of medicine each of you said you were prescribed to treat your medical condition. What you share today will help inform FDA's communications about these medicines. This discussion will last about 90 minutes.

Because we are talking about prescription medicines you are taking, I want to confirm that you have a list of medicines that you take as a reference.

There are a few things I'd like to go over to help make our discussion more productive:

- I have a discussion guide in front of me that includes all the points I want to hear your thoughts about and helps me keep the discussion on track. It is important that we cover all the topics. Therefore, I may have to break off the conversation to move to another topic area.
- We are audio and video recording this session for use in preparing a report with our findings. Because we are recording this meeting, I ask that you speak loudly and clearly. Also, please do your best to minimize background noise by finding a quiet location away from others and muting any devices such as TVs, music, and phones.
 - Similarly, because of the nature of an online discussion, I ask that you please speak one at a time. I want to hear what everyone has to say today as well as when I go back to listen to the audio recording to write the report.
 - If you are quiet throughout the group I may call on you to make sure that your opinions are heard.
- There are a few people online with us today. One person, [NAME], is here for technical support and will help you troubleshoot any issues that may arise during the session. Please use the chat function to get any help with technical problems. There are also others from the research team, including from the FDA, who are listening in to the session. Even though people are listening, please speak openly. We are here to learn from you and are interested in what is being said, not who is saying what.
- There are no wrong answers to anything we will ask you about. We want to hear every viewpoint, so don't hesitate to speak up if you have opinions different from what others say.

- All of you received and signed the consent forms. As a reminder, your contributions to our discussion will be secure to the extent permitted by law, and your names will not be provided to the FDA or appear in any reports we write for them. Likewise, we will not share any of our discussion with others not actively working on this project. We also ask that you do not share information about our discussion today with other people outside of this focus group.
- Your participation is voluntary. You can choose not to answer any question you do not wish to answer. Also, at any point in time you may stop participating.

Does anyone have any questions before we begin?

Icebreaker

First, I'd like everyone to introduce themselves. Can you each share your first name and what you like to do in your free time?

Thank you. Now we're going to talk about your thoughts and experiences related to biological products, also called biologics.

Section 2: Knowledge of Biologics (7 minutes)

When we scheduled each of you for this discussion, you told us that you had taken a type of medicine called a biological product, also known as a biologic.

- What, if anything, do you know about biologics?
- Where did you first learn or hear about biologics?
- What do you know about differences between biologics and other types of medicines?

When we contacted each of you to be part of this focus group, you told us that you are currently taking or have recently taken a biologic to treat [TYPE OF CONDITION]. We'd like to focus our discussion today on your experiences with and thoughts about the biologic medicines used to treat this condition, rather than focusing on your experiences with the condition itself. However, feel free to share information you think is important for understanding the context of your responses.

To make sure we're all on the same page, I'd like to show you a definition of a biologic. [Moderator: Share definition on screen and read aloud]

Biological Product Description

Biological products (also called biologics) are a diverse category of products used to diagnose, prevent, treat, and cure diseases and medical conditions. They are generally large, complex molecules that may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell.

FDA has approved many types of biological products for use in the United States. Most biologics are administered to patients by infusion through an IV (an injection through a vein) or by an injection under the skin or into a muscle. There are a few biologics that come in pill form as well.

I'll show you a list of biologic drugs that are used to treat the medical condition(s) for today's group. [Moderator: Show names on screen for reference, in bullet point or grid format]

[ANEMIA GROUP]

- Biologics that treat anemia include Aranesp, Epogen, Erythropoietin, Mircera, Omontys, Procrit, and Retacrit.

[ARTHRITIS GROUPS]

- Biologics that treat various types of arthritis include Actemra, Cimzia, Cosentyx, Enbrel, Humira, Inflectra, Kevzara, Kineret, Orencia, Otezla, Remicade, Renflexis, Rituxan, Simponi, Stelara, Taltz, and Xeljanz.

[CANCER GROUPS]

- Biologics that treat leukemia include Arzerra, Asparlas, Besponsa, Blincyto, Campath, Elspar, Erwinaze, Gazyva, Intron A, Kymriah, Lumoxiti, Mylotarg, Oncaspar, Rituxan, Rituxan Hycela, and Truxima.
- Biologics that treat lymphoma and myeloma include Adcetris, Darzalex, Empliciti, Erwinaze, Gazyva, Keytruda, Kymriah, Ontak, Rituxan, Rituxan Hycela, Truxima, and Zevalin.
- Biologics that treat lung cancer include Avastin, Bavencio, Cyramza, Imfinzi, Keytruda, Opdivo, Portrazza, and Tecentriq.
- Biologics that treat skin cancer (melanoma, squamous cell carcinoma, and basal cell carcinoma) include Alferon N, Keytruda, Libtayo, Opdivo, Proleukin, and Yervoy.
- Biologics that treat colorectal cancer include Avastin, Cyramza, Erbitux, Vectibix, Yervoy, and Zaltrap.
- Biologics that treat breast cancer include Herceptin, Kadcylla, Perjeta, and Tecentriq.
- Biologics that treat kidney cancer include Avastin, Opdivo, Proleukin, and Yervoy.
- Biologics that treat other types of cancer include Avastin, Cyramza, Erbitux, Keytruda, Lartruvo, and Mvasi.
- For neutropenia (which is low white blood cell count) associated with cancer treatment, some biologics include Fulphila, Granix, Neulasta, Neupogen, Nivestym, Udenyca, and Zarxio.

[DERMATOLOGICAL/SKIN CONDITION GROUPS]

- Biologics that treat various skin conditions include Cimzia, Cosentyx, Dupixent, Enbrel, Humira, Ilumya, Otezla, Remicade, Renflexis, Stelara, Taltz, Tremfya, and Siliq.

[GLOMERULONEPHRITIS/VASCULITIS GROUP]

- Rituxan is the only currently approved biologic for glomerulonephritis and vasculitis.

[INFLAMMATORY BOWEL DISEASE GROUPS]

- Biologics that treat Crohn's disease and ulcerative colitis include Cimzia, Entyvio, Humira, Inflectra, Renflexis, Remicade, Simponi, Stelara, Tysabri, and Xeljanz.
- What biologics are you currently taking or have you taken in the last six months for [CONDITION]?

- o How do you take them?
 - [If needed] For example, through an injection or shot under the skin or into a muscle? An intravenous or IV infusion, which involves a needle inserted into a vein?
 - o How often do you take/receive them?
- What do you know about the specific biologic medicines that you have taken or are currently taking?

Section 3: Thoughts, Experiences, and Desired Information Related to Biologics (30 minutes)

Now I'd like to ask you some questions about your experience with biologics and what you think about them, and what information you would like to have about them.

[Note to moderator: If participant specifically discusses biosimilars during this section, please ask them to save their thoughts until the next section of discussion.]

Thoughts, Experiences, and Attitudes Related to Biologics

- What are your general thoughts about taking a biologic?
 - o Are your thoughts about taking a biologic different from how you think about taking other drugs? If so, how?
- How has your experience been with taking a biologic?
 - o What do you like about biologics?
 - o What do you dislike about biologics?
 - o Have any of you ever stopped taking your biologic? For what reason(s)?
 - o How does taking a biologic compare to taking other drugs or treatments?
 - o How do the results of taking a biologic compare to taking other drugs or treatments?
- When you were starting on a biologic medicine, how did your health care provider explain it to you?
 - o What did he or she say were the benefits of this medicine?
 - o How did he or she say it compared to other medicines you were taking for this condition/disease?
 - o What did he or she tell you about side effects with this medicine?
 - o What did he or she say that made it easier to understand this explanation? What made it harder to understand?
 - o What questions did you ask your provider about the medicine? What questions about the medicine didn't you ask your provider? Why?
 - o How did you get answers to these questions? What questions did you still have about this medicine?
 - o What concerns did you have about the medicine that you talked with your provider about?

- o What concerns did you have that you didn't ask your provider about? Why? How did you resolve these concerns?
- o How much time did your provider spend talking with you about the medicine? How did you feel about your provider's explanation about this medicine? About the amount of time he or she spent talking with you about it?
- When you were considering starting a biologic as a treatment option, what factors did you consider?
 - o What factors were the most important in your decision-making process?
 - o How did you feel about starting this medicine?
- What other information did your health care provider share with you about biologics?
 - o What written information did your health care provider give you to read, if any? To take home with you?
 - o What patient resources did your provider offer to you, if any?
 - o What were your thoughts on this material?
 - o How easy or difficult was it to understand this material?
 - o What questions about biologics did you have that weren't answered by this material?
- Did you seek out any additional information about the specific medicine or biologics in general?
 - o Where did you go to look for this information?

Now I'd like to discuss more details about what kind of information you would want and need about biologics.

Desired Information About Biologics

- What information would you like to have had when you were first considering taking biologics?
 - o What level of detail would you prefer for this information?
 - o What sources would you have liked to receive this information from? For example, from your doctor, a patient group, a government agency, or some other source?
 - o What sources of information do you consider to be more trustworthy?
 - o Would you look for information about biologics from the FDA? Why or why not?
 - What are your thoughts about the FDA as a source of information on medical products?

- What are the three most important pieces of information someone should know about biologics before taking them?
 - o What makes this information a priority to you?
- What questions or concerns do you currently have about taking biologics?
 - o What information would help to address your questions or concerns about biologics?
- What information would you need to explain biologics to other patients or someone else, like a friend or family member, who might need to take them?
- In what format would you prefer to receive information about biologics?
 - o For example, a physical handout or pamphlet, website, video?
 - o Ideally, what would the information in that format look like? How long would it be?
 - o For what reasons would you like to receive information about biologics through that format?

Section 4: Knowledge, Thoughts, Experiences, and Desired Information Related to Biosimilars (25 minutes)

Now we'd like to discuss a specific type of biologic, known as a biosimilar product. These are also referred to as biosimilars.

Knowledge about Biosimilars

- How many of you have heard of biosimilar products?
 - o [Moderator: Show names on screen for reference] The current biosimilars that are available on the market are called Renflexis, Inflectra, Zarxio (ZAR-zee-o), Fulphila (FUL-fih-luh), Nivestym (Neye-ves-tim), Retacrit, and Udenyca.
 - o Have any of you heard of these biosimilars?
 - What do you know about them?
 - o Have any of you been prescribed one of these biosimilars?
 - Did you end up taking the biosimilar? Why or why not?
 - o For those of you who have heard of or been prescribed biosimilar products, what do you know about them, in general?
 - What is your understanding of what a biosimilar is?
 - Where did you learn this information?

Thoughts, Experiences, and Attitudes Related to Biosimilars

[Proceed with rest of biosimilars sections only if anyone has been prescribed a biosimilar or has familiarity with them]

I'd now like to discuss your thoughts about and experiences with biosimilars in more detail. As a reminder, the currently available biosimilars are Renflexis, Inflectra, Zarxio, Fulphila, Nivestym, Retacrit, and Udenyca.

- What are your general thoughts about taking a biosimilar?
 - o Are your thoughts about taking a biosimilar different from how you think about taking other biologics? If so, how?
- For those of you who have taken a biosimilar, how has your experience been with taking it?
 - o What do you like about biosimilars?
 - o What do you dislike about biosimilars?
 - o Have any of you stopped taking your biosimilar? For what reasons did you stop taking this biosimilar?
 - o How does taking a biosimilar compare to other drugs or treatments?

- For those who have been prescribed a biosimilar, was this the first biologic you had been prescribed to treat this condition, or were you switching from the original biologic that the biosimilar is compared to.
 - o How did your health care provider discuss the switch in medicines?
 - o How did you feel about switching?
 - o For those who switched from the original biologic, how was your experience with switching to the biosimilar?
- When you were considering starting a biosimilar as a treatment option, what factors did you consider?
 - o What factors were the most important in your decision-making process?
- For those of you who have been prescribed a biosimilar, did your health care provider share any information specifically about the product being a biosimilar?
 - o What information did you learn?
 - o How easy or difficult was it to understand this explanation?
 - o How did you feel about your provider's explanation about the biosimilar?
 - o What questions did you have about biosimilars that your health care provider was able to answer?
 - o What other information did your health care provider share with you about biosimilars?
 - What written information did your health care provider give you to read, if any? To take home with you?

Now I'd like to discuss more details about what kind of information you would want and need about biosimilars.

Desired Information About Biosimilars

- What information would you like to have if you were first considering taking a biosimilar?
 - o What information would be most important to know about biosimilars?
 - o What sources would you have liked to receive this information from? For example, from your doctor, a patient group, a government agency, or some other source?
 - o Would you look for information about biosimilars from the FDA? Why or why not?
- What are the three most important pieces of information someone should know about biosimilars before taking them?

- o What makes this information a priority to you?
- What questions or concerns do you have about biosimilars?
 - o What information would help to address your questions or concerns about biosimilars, specifically?
- What information would you need to explain biosimilars to other patients or someone else, like a friend or family member, who might need to take them?
- In what format would you prefer to receive information about biosimilars?
 - o For example, a physical handout or pamphlet, website, video?
 - o Ideally, what would the information in that format look like? How long would it be?
 - o For what reasons would you like to receive information about biologics through that format?

Knowledge About Interchangeable Products

- How many of you have heard of a particular type of biologic called an interchangeable product?
 - o What do you know about them?
 - o What is your understanding of what an interchangeable product is?

Thank you. We won't be discussing interchangeable products in detail today because none have been approved in the United States yet, but I wanted to know if any of you had heard of them before.

Section 5: Biosimilar and Interchangeable Product Educational Materials (15-18 minutes)

For the last section of today's focus group discussion, we have some information about biosimilar and interchangeable products that we'd like to get your reactions to, which I'm going to put up on the screen now for you to look at. These draft materials are intended for patients like yourselves. Please take a few minutes to read this now and then I'll ask you some questions about it.

[Based on the pre-designated randomization, the moderator will show the designated material to the group by pulling it up on the screen. The moderator will allot a few minutes for the participants to read the material on their screens. Afterwards, the moderator will ask a series of questions.]

Questions in *italics* should be asked if there is sufficient time for this section of the discussion. With limited time, only ask questions in normal font.]

Each group will view either:

- One overview infographic OR
- Two print PSAs

[Moderator: If presenting the two PSAs, ask questions for only the first PSA. Present second PSA briefly before asking comparison questions.]

I'm going to get started on the discussion questions, but will keep the information up on the screen for you to reference.

- What are the main ideas that you took away from this information?
- What are your thoughts about this information and how it is presented?
 - What do you like about it?
 - What do you dislike about it?
- *If you saw this [infographic or PSA] online or at your doctor's office or a health fair, what would you do?*
 - **[IF NEEDED]** *Pick it up, read it, pay attention, ignore it, act on it, etc.*
 - *What is it about the [infographic or PSA] that would make you do that?*
- *How did this information affect your understanding of what biosimilars are?*
- *How did this information affect your understanding of what interchangeable products are?*
- How easy was it for you to understand this information?
 - What would make this information easier to understand?

- Was there anything unclear or confusing about this information?
 - o What was unclear or confusing?
- *To what extent does this information address any questions or concerns you have about biosimilars?*
 - o *What other information would help to address your questions or concerns?*
- **[Ask following questions for overview infographic only]**
 - o *What does the phrase “a biosimilar has no clinically meaningful differences from a reference product” mean to you? [Point out the phrase on the infographic]*
 - o *What do you think about the alternate phrase “a biosimilar has comparable safety and efficacy to a reference product”? [Show phrase on screen]*
 - *What does that term “efficacy” mean to you?*
 - o *What do you think about the alternate phrase “a biosimilar has similar safety and efficacy to a reference product”? [Show phrase on screen]*
 - o *What do you think about the phrase “prescribers and patients should have no concerns”? [Point out the phrase on the infographic]*
 - *What do you think about the alternate phrase “prescribers and patients should be comfortable”? [Show phrase on screen]*
 - o *What are your thoughts on the images in this handout?*
- What changes would you recommend to improve this material?
- Would this information change your likelihood or willingness to use a biosimilar product?
 - o Why or why not?

[Moderator: Proceed with next section only if conducting comparison between two versions of PSAs]

- Now I'm going to show you a different version of the same PSA. What differences do you notice?
- I'd like to get your opinions on which of the two PSAs you preferred. Could I get a show of hands from who prefers the version on the left? How about a show of hands from who prefers the version on the right?
- For those of you who preferred A, could you tell me some reasons why you prefer this one?
- For those of you who preferred B, could you tell me some reasons why you prefer this one?

Section 6: Conclusion (5 minutes)

Thank you very much for participating in this focus group. I appreciate you sharing your time and valuable feedback. Is there anything that you would like to share that you did not have a chance to share yet?

[The moderator will check with the research team for any remaining questions.] If you will excuse me for just a moment, I would like to check with the members of my team who have been listening to this discussion to see if they have any follow-up questions for you.

I believe we are all done here. Thank you so much for your time. You will receive your incentive through FieldGoals. If you don't, please follow up with FieldGoals. If you have other questions about the research, please use the contact information for our researchers on the consent form copy you were provided.

