

# FDA Biosimilars Study

## Focus Group Participant Screener

### Healthcare Providers

#### Introduction

Hello, \_\_\_\_\_. My name is \_\_\_\_\_, and I'm calling you on behalf of the U.S. Department of Health and Human Services (DHHS) about a research study. DHHS will be conducting several focus groups at [organization] on the topic of biological drug products.

To see if you're eligible, I'd like to ask you some questions. If you're eligible and choose to participate, you will be invited to join a focus group at [BSWH / TBD] and will be compensated [\$300 / \$225] for your time.

May I proceed with my questions?

- Yes → CONTINUE
- No → TERMINATE

#### Employment Questions

1. Have you, your family members, or anyone in your household ever worked for any of the following organizations? [Read response options]

U.S. Food and Drug Administration (FDA)		→ TERMINATE
National Institutes of Health (NIH)		→ TERMINATE
Centers for Medicare and Medicaid Services (CMS)		→ TERMINATE
U.S. Department of Health and Human Services Agencies		→ TERMINATE
Pharmaceutical company [Do not count consulting]		→ TERMINATE
None of the above		→ CONTINUE

2. Which of the following best describes your occupation? [Read response options]

Physician (MD, DO)		→ CONTINUE
Pharmacist (PharmD)		→ SKIP TO Q8
Nurse Practitioner / Physician Assistant		→ SKIP TO Q12
Other healthcare provider (e.g., nurse)		→ TERMINATE

## Physician Questions

3. Which type of medical degree do you hold? [Read response options]

Doctor of Medicine (MD)		→ CONTINUE
Doctor of Osteopathic Medicine (DO)		→ CONTINUE
Other degree (specify)		→ HOLD

4. In which country did you receive your medical degree?

USA		→ CONTINUE
Other (specify)		→ CONTINUE

5. In what medical specialty do you currently practice? [Select one response]

Rheumatology		→ CONTINUE [GROUP A]
Oncology		→ CONTINUE [GROUP B]
Hematology		→ CONTINUE [GROUP B]
Dermatology		→ CONTINUE [GROUP C]
Nephrology		→ CONTINUE [GROUP C]
Other (specify)		→ TERMINATE

6. In which medical settings do you currently practice? [Select all that apply]

Community Hospital		→ CONTINUE
Academic Hospital		→ CONTINUE
Outpatient Clinic		→ CONTINUE
Private / Group Practice		→ CONTINUE
Other Outpatient Setting (e.g., infusion center, dialysis clinic)		→ CONTINUE
Other (specify)		→ HOLD

7. [If selected more than one in Q6] In which medical setting do you practice most often? [Select one response]

Community Hospital		→ SKIP TO Q16
Academic Hospital		→ SKIP TO Q16
Outpatient Clinic		→ SKIP TO Q16
Private / Group Practice		→ SKIP TO Q16
Other Outpatient Setting (e.g., infusion center, dialysis clinic)		→ SKIP TO Q16
Other (specify)		→ HOLD

### Pharmacist Questions

8. In which country did you receive your pharmacy degree?

USA		→ CONTINUE
Other (specify)		→ CONTINUE

9. Did you complete additional training beyond your pharmacy degree, such as a residency or fellowship?

Yes		→ CONTINUE
No		→ CONTINUE

10. In which pharmacy settings do you currently practice? [Select all that apply]

Community Hospital		→ CONTINUE
Academic Hospital		→ CONTINUE
Community Pharmacy / Chain Drug Store		→ CONTINUE
Outpatient Clinic		→ CONTINUE
Other Outpatient Setting		→ CONTINUE
Other (specify)		→ HOLD

11. [If selected more than one in Q10] In which pharmacy setting do you practice most often?  
[Select one response]

Community Hospital		→ SKIP TO Q16
Academic Hospital		→ SKIP TO Q16
Community Pharmacy / Chain Drug Store		→ SKIP TO Q16
Outpatient Clinic		→ SKIP TO Q16
Other Outpatient Setting		→ SKIP TO Q16
Other (specify)		→ HOLD

**Nurse Practitioner / Physician Assistant Questions**

12. Do you currently have authority to prescribe medications to patients in your workplace?

Yes		→ CONTINUE
No		→ TERMINATE

13. In what medical specialty do you currently practice? [Select one response]

Rheumatology		→ CONTINUE
Oncology		→ CONTINUE
Hematology		→ CONTINUE
Dermatology		→ CONTINUE
Nephrology		→ CONTINUE
Other (specify)		→ TERMINATE

14. In which medical settings do you currently practice? [Select all that apply]

Community Hospital		→ CONTINUE
Academic Hospital		→ CONTINUE
Outpatient Clinic		→ CONTINUE
Private / Group Practice		→ CONTINUE
Other Outpatient Setting (e.g., infusion center, dialysis clinic)		→ CONTINUE
Other (specify)		→ HOLD

15. [If selected more than one in Q14] In which medical setting do you practice most often? [Select one response]

Community Hospital		→ CONTINUE
Academic Hospital		→ CONTINUE
Outpatient Clinic		→ CONTINUE
Private / Group Practice		→ CONTINUE
Other Outpatient Setting (e.g., infusion center, dialysis clinic)		→ CONTINUE
Other (specify)		→ HOLD

**Practice Questions (All Audience Segments)**

16. In an average year, what percentage of your work time is spent on patient care? Patient care activities include examining patients, performing diagnostic tests, prescribing or dispensing medications, reviewing patient records, and other activities directly connected to treatment. Non-patient care activities include teaching, research, and administration.

____%	<b>50% or More → CONTINUE</b> <b>Less than 50% → TERMINATE</b>
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17. How many patients have you [prescribed (for physicians, NPs, and PAs) / dispensed (for pharmacists)] biological products to within the last 2 months? This can include either new or recurring prescriptions.

Biological products are medications derived from a living organism, such as humans, animals, micro-organisms, or yeast.

—	<b>Five or More → CONTINUE</b> <b>Four or Fewer → TERMINATE</b>
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18. How many different types of biological products have you [prescribed (for physicians, NPs, and PAs) / dispensed (for pharmacists)] in the past year?

—	<b>Two or More → CONTINUE</b> <b>One / None → TERMINATE</b>
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19. How long have you been practicing as a [physician, pharmacist, nurse practitioner, physician assistant]?

___ years	<b>→ CONTINUE</b>
<b>QUOTAS:</b> <ul style="list-style-type: none"> <li>• <b>Minimum of 2 participants per group 10 years or less</b></li> <li>• <b>Minimum of 2 participants per group 11-20 years</b></li> <li>• <b>Minimum of 2 participants per group 21 years or more</b></li> </ul>	

20. Do you currently serve—or have you ever served—on a Pharmacy and Therapeutic (P&T) or Drug Formulary committee?

<b>Currently Serve</b>		<b>→ CONTINUE</b>
<b>Previously Served</b>		<b>→ SKIP TO Q22</b>
<b>Never Served</b>		<b>→ SKIP TO Q23</b>

21. How long have you served on the P&T/Formulary committee?

___ years	<b>→ SKIP TO Q19</b>
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22. How long did you serve on the P&T/Formulary committee?

___ years	→ CONTINUE
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### Demographic Questions

23. What is your gender?

Male		→ CONTINUE
Female		→ CONTINUE
<b>QUOTAS:</b> <ul style="list-style-type: none"><li>• Minimum of 3 males per group</li><li>• Minimum of 3 females per group</li></ul>		

24. In what year were you born?

_____	→ CONTINUE
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25. Are you of Hispanic, Latino, or Spanish origin?

Yes		→ CONTINUE
No		→ CONTINUE

26. What is your race? You may choose one or more categories as they apply. [Read response options]

White		→ CONTINUE
Black / African American		→ CONTINUE
American Indian or Alaskan Native		→ CONTINUE
Asian		→ CONTINUE
Native Hawaiian or Pacific Islander		→ CONTINUE
Other		→ CONTINUE
<b>QUOTA: MINIMUM OF 2 NON-WHITE PARTICIPANTS PER GROUP</b>		

## Focus Group Invitation

Thank you for answering all of my questions. Based on your responses, you appear eligible to participate in our study and join one of our focus groups.

Each focus group will last approximately 90 minutes and will be audio-taped, videotaped, and observed online by DHHS staff. Your participation and everything you say during the discussion will remain confidential to the extent permitted by law. You will receive an honorarium of **[\$300 (for physicians) / \$225 (for pharmacists, nurse practitioners, and physician assistants)]** as a thank you for your time and participation.

Can I schedule your participation?

- Yes → CONTINUE
- No → TERMINATE

I'm glad that you will be able to join us! The focus group will take place on **[date]** at **[time]** at **[location]**. Will you be available to participate at this time?

- Yes → CONTINUE
- No → HOLD (IN CASE SCHEDULE CHANGES)

We would like to send a confirmation letter and directions to the group. Could you please tell me your mailing address, e-mail address, and phone number?

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_  
Phone: \_\_\_\_\_  
Email: \_\_\_\_\_  
Date of focus group: \_\_\_\_\_ Time: \_\_\_\_\_

Group A	Group B	Group C	Group D	Group E
Rheumatology	Oncology/ Hematology	Dermatology/ Nephrology	Pharmacists	Nurse Practitioners / Physician Assistants

Your participation in this study is very important. If for some reason you will not be able to attend, please let us know right away. You can call us anytime at **[phone number]**, and if we are not here, please leave a message.



### **Closing for Ineligible Individuals**

I'm sorry, but you are not eligible to participate in this study. There are many possible reasons why people are not eligible. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.