

FDA Biosimilars Study

Interview Participant Screener (Phase 2)

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 sponsoring several interviews 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 participate in an interview at [BSWH / UCI] and will be compensated [\$250 / \$175] 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		→ HOLD
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 [SEGMENT A]
Oncology		➔ CONTINUE [SEGMENT B]
Hematology		➔ CONTINUE [SEGMENT B]
Dermatology		➔ CONTINUE [SEGMENT C]
Nephrology		➔ CONTINUE [SEGMENT D]
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 Q12
Academic Hospital		→ SKIP TO Q12
Outpatient Clinic		→ SKIP TO Q12
Private / Group Practice		→ SKIP TO Q12
Other Outpatient Setting (e.g., infusion center, dialysis clinic)		→ SKIP TO Q12
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		→ CONTINUE
Academic Hospital		→ CONTINUE
Community Pharmacy / Chain Drug Store		→ CONTINUE
Outpatient Clinic		→ CONTINUE
Other Outpatient Setting		→ CONTINUE
Other (specify)		→ HOLD

Practice Questions (All Audience Segments)

12. 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.

___%	50% or More → CONTINUE Less than 50% → TERMINATE
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13. How many patients have you [prescribed (for physicians) / 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.

—	Five or More → CONTINUE Four or Fewer → TERMINATE
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14. How many different types of biological products have you [prescribed (for physicians) / dispensed (for pharmacists)] in the past year?

—	Two or More → CONTINUE One / None → TERMINATE
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15. How long have you been practicing as a [physician, pharmacist]?

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

Currently Serve		→ CONTINUE
Previously Served		→ SKIP TO Q18
Never Served		→ SKIP TO Q19

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

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

___ years	→ CONTINUE
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Demographic Questions

19. What is your gender?

Male		→ CONTINUE
Female		→ CONTINUE

20. In what year were you born?

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

Yes		→ CONTINUE
No		→ CONTINUE

22. 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

Interview Invitation

Thank you for answering all of my questions. Based on your responses, you appear eligible for our study and we would like to invite you to participate in an interview.

Each interview will last approximately 60 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 [\$250 (for physicians) / \$175 (for pharmacists)] as a thank you for your time and participation.

Can I schedule your participation?

- Yes ➔ CONTINUE
- No ➔ TERMINATE

Segment A	Segment B	Segment C	Segment D	Segment E
Rheumatology	Oncology/ Hematology	Dermatology	Nephrology	Pharmacy

I'm glad that you will be able to join us! We're planning to hold the interviews during the following times: [Provide timeframe]. What dates and times during that period would be best for you?

- Option #1 Date: _____ Time: _____
- Option #2 Date: _____ Time: _____
- Option #3 Date: _____ Time: _____
- Option #4 Date: _____ Time: _____

We also 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: _____

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.