Studies to Enhance FDA Communications Addressing Biosimilar Drug Products: **Patient Interview Screener**

OMB# 0910-0695 Exp. 3/31/2024

[Display at bottom of Introduction screen]

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Biosimilars Patient Study

Phase 2 Web Screener

Introduction

Thank you for your interest in this study sponsored by the U.S. Food and Drug Administration. Please answer the following questions to see if you are eligible to participate in an online interview about health-related materials for a specific type of medicine.

The interview will be led by a researcher through an online video platform. If you're eligible for the interview, you can participate from home using a computer and web camera. The discussion will last about 90 minutes. You will be emailed about your \$75 honorarium within one business day after the interview concludes and have the option to choose between a physical or electronic gift card.

To determine your eligibility for this study, we need to ask you a few questions. These questions should take no more than 5 minutes.

1. What is your age?

Age 18 or older	
Under 18	
years [Allow 1-99]	

2. Have you ever worked...? [Accept multiple responses.]

For a drug or pharmaceutical company
For a market research or marketing company, including RTI
International or L&E Research
For the U.S. federal government (not including as a member
of the military)
As a medical professional (such as a physician, nurse, or
pharmacist)

→ TERMINATE
→ TERMINATE

3. When was the last time you participated in an interview or a focus group for a research study?

Within the last 6 months
More than 6 months ago
Never

→ TERMINATE
→ CONTINUE
→ CONTINUE

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Don't know

→ TERMINATE

4. To participate in this study, you will need a desktop computer, laptop computer, or a tablet (not just a smartphone). Which type of device are you most likely to use if you participate in the study?

Desktop computer	→ CONTINUE
Laptop computer	→ CONTINUE
Tablet (e.g., iPad)	→ CONTINUE
I don't have any of the devices listed above	→ TERMINATE

5. To participate in this study, you will also need a webcam (attached or built into the device) and high-speed Internet access. Can you meet these requirements?

Yes	→ CONTINUE
No	→ TERMINATE

6. Do you have any vision, hearing, or speaking issues that would prevent you from reviewing English-language written materials and videos during the interview?

Yes	→ TERMINATE
No	

7. Are you okay with being audio and video recorded during the interview?

Yes	
No	→ TERMINATE

8. Has a healthcare professional ever diagnosed you with any of the following medical conditions? [Accept multiple responses.]

Ankylosing spondylitis / Spondyloarthritis	→ Ask Q9, then CONTINUE to Q14
Psoriatic arthritis	→ Ask Q9, then CONTINUE to Q14
Rheumatoid arthritis	→ Ask Q9, then CONTINUE to Q14
Cancer	→ Ask Q9, then CONTINUE to Q10
Crohn's disease	→ Ask Q9, then CONTINUE to Q14
Ulcerative colitis	→ Ask Q9, then CONTINUE to Q14
Eczema / Atopic dermatitis	→ Ask Q9, then CONTINUE to Q14
Psoriasis	→ Ask Q9, then CONTINUE to Q14
Type 1 diabetes	→ Ask Q9, then CONTINUE to Q12
Type 2 diabetes	→ Ask Q9, then CONTINUE to Q12

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None of the above	→ SKIP to Q14

9. How long ago were you diagnosed with [condition]? [Ask for each condition selected by respondent] [Allow 1-99 years and 0-12 months]

____ years ____ months (if less than 1 year)

10. Which type(s) of cancer were you diagnosed with? [Accept multiple responses]

Breast	□ → CONTINUE
Colorectal	□ → CONTINUE
Kidney	□ → CONTINUE
Leukemia	□ → CONTINUE
Lung	□ → CONTINUE
Lymphoma	□ → CONTINUE
Myeloma	□ → CONTINUE
Skin	□ → CONTINUE
Other (please specify)	□ → CONTINUE

11. Have you ever been diagnosed by a healthcare professional with neutropenia, a bloodrelated side effect of chemotherapy?

Yes	→ CONTINUE to Q14
No	→ CONTINUE to Q14

12. How long have you been using insulin to treat your diabetes?

More than one month	
Less than one month	
Not currently taking insulin	

13. Do you take insulin at least once per day?

Yes	
No	

→ SKIP to Q14
 → SKIP to Q14

→ CONTINUE

→ CONTINUE to Q14
→ CONTINUE to Q14

14. Are you the parent or guardian of a child who has been diagnosed with diabetes by a healthcare professional? If so, which type of diabetes?

Yes, type 1 diabetes	→ CONTINUE
Yes, type 2 diabetes	→ CONTINUE
No	→ SEE Q19 INSTRUCTIONS

15. What is this child's age?

____ years [Allow 1-99]

Age 18 or older	→ TERMINATE IF Q8=None of the above
Under 18	

16. How involved are you in managing your child's diabetes (e.g., scheduling doctor's appointments, making medication decisions, administering insulin)?

Extremely involved	
Frequently involved	
Somewhat involved	→ SEE Q19 INSTRUCTIONS
Not at all involved	→ SEE Q19 INSTRUCTIONS

17. How long has your child been using insulin to treat his or her diabetes?

More than one month	
Less than one month	→ SEE Q19 INSTRUCTIONS
Not currently taking insulin	→ SEE Q19 INSTRUCTIONS

18. Does your child take insulin at least once per day?

Yes	→ SEE SKIP PATTERN BELOW
No	→ SEE SKIP PATTERN BELOW

[Skip pattern:

- If individual's responses have checked one or more of the yellow boxes, proceed to Q19.
- If individual's responses have checked only the green boxes, skip to Q21
- If no yellow or green boxes selected, terminate and display closing script.]
- 19. These next questions ask about medicines that you take for your health condition(s). Have you ever taken one or more of the following medicines to treat [display condition(s) based on responses to Q8, Q10, and Q11]?

[Display list of medications <u>only</u> for applicable medical conditions in Q8, Q10, and Q11.]

[Allow multiple responses. If one or more medications selected, continue to Q20. If no medications selected, terminate.]

[RECRUIT AT LEAST 20% TAKING AT LEAST ONE BIOSIMILAR]

List of Medicines for Q19

Condition	Medicines Brand Name [pronunciation] [generic Name]
Ankylosing Spondylitis/ Spondyloarthritis	 Avsola [av-SO-luh] [infliximab-axxq] (biosimilar) Cimzia [SIM-zi-ah] [certolizumab] Cosentyx [koh-SEN-tix] [secukinumab] Enbrel [EN-brel] [etanercept] Erelzi [Ee-REL-zee] [etenercept-szzs] (biosimilar) Eticovo [Et-uh-co-vo] [etanercept-ykro] (biosimilar) Humira [hu-MEER-ah] [adalimumab]

	Inflectra [In-flec-tra] [infliximab-dyyb] (biosimilar) Ixifi [ix-IF-ee] [infliximab-qbtx] (biosimilar) Remicade [REM-i-cade] [infliximab] Renflexis [ren-FLEX-is] [infliximab-abda] (biosimilar) Simponi [SIM-poh-nee] [golimumab] Taltz [Taltz] [xekixumab]
Psoriatic Arthritis	Avsola [av-SO-luh] [infliximab-axxq] (biosimilar) Cimzia [SIM-zi-ah] [certolizumab] Cosentyx [koh-SEN-tix] [secukinumab] Enbrel [EN-brel] [etanercept] Erelzi [Ee-REL-zee] [etenercept-szzs] (biosimilar) Eticovo [Et-uh-co-vo] [etanercept-ykro] (biosimilar) Humira [hu-MEER-ah] [adalimumab] Inflectra [In-flec-tra] [infliximab-dyyb] (biosimilar) Ixifi [ix-IF-ee] [infliximab-qbtx] (biosimilar) Orencia [oh-REN-see-ah] [abatacept] Otezla [oh-TEZ-la] [apremilast] Remicade [REM-i-cade] [infliximab] Renflexis [ren-FLEX-is] [infliximab-abda] (biosimilar) Simponi [SIM-poh-nee] [golimumab] Simponi Aria [golimumab], IV Infusion Stelara [stuh-LAIR-ah] [ustekinumab] Taltz [Taltz] [xekixumab] Xeljanz [ZEL-janz] [tofacitinib]
Rheumatoid Arthritis	Actemra [ac-tEm-ra] [tocilizumab] Avsola [av-SO-luh] [infliximab-axxq] (biosimilar) Cimzia [SIM-zi-ah] [certolizumab] Cosentyx [koh-SEN-tix] [secukinumab] Enbrel [EN-brel] [etanercept] Erelzi [Ee-REL-zee] [etenercept-szzs] (biosimilar) Eticovo [Et-uh-co-vo] [etanercept-ykro] (biosimilar) Humira [hu-MEER-ah] [adalimumab] Inflectra [In-flec-tra] [infliximab-dyyb] (biosimilar) Ixifi [ix-IF-ee] [infliximab-qbtx] (biosimilar) Kevzara [kev-ZAR-a] [sarilumab] Kineret [KIN-er-et] [anakinra] Orencia [oh-REN-see-ah] [abatacept] Remicade [REM-i-cade] [infliximab-abda] (biosimilar) Rinvoq [RIN-voke] [upadacitinib] Rituxan [rih-TUK-sun] [rituximab] Stelara [stuh-LAIR-ah] [ustekinumab] Simponi [SIM-poh-nee] [golimumab] Xeljanz [ZEL-janz] [tofacitinib]
Cancer (leukemia)	Arzerra [ar-ZAYR-uh] [ofatumumab] Asparlas [AS-par-las] [calaspargase pegol-mknl] Besponsa [beh-SPON-suh] [inotuzumab ozogamicin]

	 Blincyto [blin-sye-toe] [blinatumomab] Campath [KAM-path] [alemtuzumab] Copiktra [koh-PIK-truh] [duvelisib] Daurismo [DOOR-is-moh] [glasdegib] Elspar [EL-spar] [asparaginase] Erwinaze [ER-wih-nayz] [asparaginase erwinia chrysanthemi] Gazyva [guh-ZY-vuh] [obinutuzumab) Intron A [IN-tron-Aye] [interferon alfa-2b] Kymriah [kim-rye-ah] [tisagenlecleucel] Lumoxiti [loo-MOK-sih-tee] [moxetumomab pasudotox-tdfk] Mylotarg [MY-loh-targ] [gemtuzumab ozogamicin] Oncaspar [ON-kah-spar] [pegaspargase] Riabni [re-AB-nee] [rituximab-arrx] (biosimilar) Rituxan [rih-TUK-sun] [rituximab] Rituxan Hycela [rih-TUK-sun hy-SEL-uh] [rituximab and hyaluronidase human] Ruxience [RUKS-ee-ents] [rituximab-abbs] (biosimilar) Yenclexta [ven-KLEK-stuh] [venetoclax] Xospata [zoh-SPAH-tuh] [gilteritinib]
Cancer (blood – including lymphoma and myeloma)	 Adcetris [ad-SEH-tris] [brentuximab vedotin] Blenrep [BLEN-rep] [belantamab mafodotin-blmf] Darzalex [DAR-zah-lex] [daratumumab] Darzalex Faspro [DAR-zah-lex Fass-pro] [daratumumab and hyaluronidase-fihj] Empliciti [em-PLIH-sih-tee] [elotuzumab] Epogen [EE-po-jen] [epoetin alfa] Erwinaze [ER-wih-nayz] [asparaginase erwinia chrysanthemi] Gazyva [guh-ZY-vuh] [obinutuzumab] Keytruda [key-true-duh] [pembrolizumab] Kymriah [kim-rye-ah] [tisagenlecleucel] Monjuvi [mon-JOO-vee] [tafasitamab-cxix] Ontak [ON-tak] [denileukin diftitox] Polivy [poh-LIH-vee] [polatuzumab vedotin-piiq] Procrit [PROH-crit] [epoetin alfa] Retacrit [RET-a-crit] [epoetin alfa-epbx] Riabni [re-AB-nee] [rituximab-arrx] (biosimilar) Rituxan Hycela [rih-TUK-sun hy-SEL-uh] [rituximab and hyaluronidase human] Ruxience [RUKS-ee-ents] [rituximab-pvvr] (biosimilar) Sarclisa [sar-KLIH-suh] [isatuximab-irfc] Tecartus [tek-AR-tus] [brexucabtagene autoleucel] Truxima [truk-SEE-muh] [rituximab-abbs] (biosimilar)
Cancer (lung)	 Avastin [uh-VAST-in] [bevacizumab] Bavencio [buh-VEN-see-oh] [avelumab] Cyramza [sy-RAM-zuh] [ramucirumab]

	 Epogen [EE-po-jen] [epoetin alfa] Imfinzi [im-FIN-zee] [durvalumab] Keytruda [key-true-duh][pembrolizumab] Lorlatinib [lor-LA-ti-nib] [lorlatinib] Mvasi [em-VAH-see] [bevacizumab-awwb] (biosimilar) Opdivo [op-DEE-voh] [nivolumab] Portrazza [por-TRA-zuh] [necitumumab] Procrit [PROH-crit] [epoetin alfa] Retacrit [RET-a-crit] [epoetin alfa-epbx] Tecentriq [teh-SEN-trik] [atezolizumab] Vizimpro [vih-ZIM-proh] [dacomitinib] Zirabev (bevacizumab-bvzr) (biosimilar) 		
Cancer (skin—melanoma, squamous cell carcinoma, basal cell carcinoma)	Alferon N [al-FEER-on N] [interferon alfa-n3] Braftovi [braf-TOH-vee] [encorafenib] Keytruda [key-true-duh] [pembrolizumab] Libtayo [lib-TY-oh] [cemiplimab-ydhp] Opdivo [op-DEE-voh] [nivolumab] Mektovi [mek-TOH-vee] [binimetinib] Proleukin [proh-LOO-kin] [aldesleukin] Yervoy [YER-voy] [ipilimumab]		
Cancer (colorectal)	 Avastin [uh-VAST-in] [bevacizumab] Cyramza [sy-RAM-zuh] [ramucirumab] Erbitux [ER-bih-tux] [cetuximab] Mvasi [em-VAH-see] [bevacizumab-awwb] (biosimilar) Vectibix [VEK-tih-bix] [panitumumab] Yervoy [YER-voy] [ipilimumab] Zaltrap [ZAL-trap] [ziv-aflibercept] Zirabev [ZIE-rah-bev] [bevacizumab-bvzr] (biosimilar) 		
Cancer (breast)	 Epogen [EE-po-jen] [epoetin alfa] Herceptin [her-SEP-tin] [trastuzumab] Herzuma [her-ZOO-muh] [trastuzumab-pkrb] (biosimilar) Kadcyla [kad-SY-luh] [ado-trastuzumab emtansine] Kanjinti [kan-jin-tee] [trastuzumab-anns] (biosimilar) Margenza [MAR-jen-zuh] [margetuximab-cmkb] Ogivri [oh-GIV-ree] [trastuzumab-dkst] (biosimilar) Ontruzant [on-TRU-zant] [trastuzumab-dttb] (biosimilar) Phesgo [FES-goh] [pertuzumab] Phesgo [FES-goh] [pertuzumab, trastuzumab, and hyaluronidase-zzxf] Procrit [PROH-crit] [epoetin alfa] Retacrit [RET-a-crit] [epoetin alfa-epbx] Talazoparib [TA-luh-ZOH-puh-rib] [talazaoparib] Trazimera [tra-zee-MER-uh] [trastuzumab-qyyp] (biosimilar) 		

Cancer (kidney)	 Avastin [uh-VAST-in] [bevacizumab] Mvasi [em-VAH-see] [bevacizumab-awwb] (biosimilar) Opdivo [op-DEE-voh] [nivolumab] Proleukin [proh-LOO-kin] [aldesleukin] Yervoy [YER-voy] [ipilimumab] Zirabev (bevacizumab-bvzr) (biosimilar)
Cancer (other types)	 Avastin [uh-VAST-in] [bevacizumab] Cyramza [sy-RAM-zuh] [ramucirumab] Danyelza [dan-YEL-zah] [naxitamab-gqg] Elzonris [el-ZON-ris] [tagraxofusp-erz] Epogen [EE-po-jen] [epoetin alfa] Erbitux [ER-bih-tux] [cetuximab] Keytruda [key-true-duh] [pembrolizumab] Lartruvo [lar-TROO-voh] [olaratumab] Lenvima [len-VEE-muh] [lenvatinib] Lynparza [lin-PAR-zuh] [olaparib] Mvasi [em-VAH-see] [bevacizumab-awwb] (biosimilar) Poteligeo [poh-teh-LIH-gee-oh] [mogamuliziumab] Procrit [PROH-crit] [epoetin alfa] Retacrit [RET-a-crit] [epoetin alfa-epbx] Tecentriq [teh-SEN-trik][atezolizumab] Zirabev (bevacizumab-bvzr) (biosimilar)
Neutropenia (from cancer treatment)	 Fulphila [FUL-fih-luh] [pegfilgrastim-jmdb] (biosimilar) Granix [GRA-nix] [tbo-filgrastim] Neulasta [noo-LA-stuh] [pegfilgrastim] Neupogen [NOO-poh-jen] [filgrastim] Nivestym [NAI-vuh-stim] [filgrastim-aafi] (biosimilar) Nyvepria [NAI-vee-pri-ah] [pegfilgrastim-apgf] (biosimilar) Udenyca [yoo-den-i-kah] [pegfilgrastim-cbqv] (biosimilar) Zarxio [ZAR-zee-oh] [filgrastim-sndz] (biosimilar) Ziextenzo [zee-ex-TEN-zo] [pegfilgrastim-bmez] (biosimilar)
Crohn's Disease	 Avsola [av-SO-luh] [infliximab-axxq] (biosimilar) Cimzia [SIM-zi-ah] [certolizumab] Entyvio [en-TIV-ee-oh] [vedolizumab] Humira [hu-MEER-ah] [adalimumab] Inflectra [In-flec-tra] [infliximab-dyyb] (biosimilar) Ixifi [ix-IF-ee] [infliximab-qbtx] (biosimilar) Ixifi [ix-IF-ee] [infliximab-qbtx] (biosimilar) Remicade [REM-i-cade] [infliximab] Renflexis [ren-FLEX-is] [infliximab-abda] (biosimilar) Stelara [ustekinumab] Tysabri [tai-SAB-ree] [natalizumab]

Ulcerative Colitis	 Avsola [av-SO-luh] [infliximab-axxq] (biosimilar) Entyvio [en-TIV-ee-oh] [vedolizumab] Humira [hu-MEER-ah] [adalimumab] Inflectra [In-flec-tra] [infliximab-dyyb] (biosimilar) Ixifi [ix-IF-ee] [Infliximab-qbtx] (biosimilar) Ixifi [ix-IF-ee] [Infliximab-qbtx] (biosimilar) Remicade [REM-i-cade] [infliximab] Renflexis [ren-FLEX-is] [infliximab-abda] (biosimilar) Simponi [SIM-poh-nee] [golimumab] Stelara [stuh-LAIR-ah] [ustekinumab] Xeljanz [ZEL-janz] [tofacitinib]
Eczema/Atopic Dermatitis	Dupixent [due-PIX-ent] [dupilumab]
Psoriasis	 Avsola [av-SO-luh] [infliximab-axxq] (biosimilar) Cimzia [SIM-zi-ah] [certolizumab] Cosentyx [koh-SEN-tix] [secukinumab] Enbrel [EN-brel] [etanercept] Erelzi [Ee-REL-zee] [etanercept-szzs] (biosimilar) Eticovo [Et-uh-co-vo] [etanercept-ykro] (biosimilar) Humira [hu-MEER-ah] [adalimumab] Ilumya [e-loom-e-a] [tildrakizumab] Inflectra [In-flec-tra] [infliximab-dyyb] (biosimilar) Ixifi [ix-IF-ee] [infliximab-qbtx] (biosimilar) Ixifi [ix-IF-ee] [infliximab-qbtx] (biosimilar) Otezla [oh-TEZ-la] [apremilast] Remicade [REM-i-cade] [infliximab] Renflexis [ren-FLEX-is] [infliximab-abda] (biosimilar) Siliq [sill-EEK] [brodalumb] Stelara [stuh-LAIR-ah] [ustekinumab] Taltz [taltz] [lxekizumab]

20. Please fill in the following information about each medicine that you selected.

[Populate first two columns based on Q19 responses]

[If currently taking any medicine for more than one month, proceed to Q21]

[If not currently taking a medicine, but the medicine was taken within the last year <u>and</u> taken for more than one month, proceed to Q21]

Medicine	Condition	Are you still taking this medicine?	YES	How long have you been taking it?	NO	When did you last take this medicine?	How long did you take this medicine when you were still using it?	
[Medicine]	[Condition]	YesNo		Less than one month		Within the last month	Less than one month	

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			 1-3 months 4-6 months 7-12 months More than one year 	 1-3 months ago 4-6 months ago More than 6 months ago 	More than or month
[Medicine]	[Condition]	☐ Yes ☐ No	 Less than one month 1-3 months 4-6 months 7-12 months More than one year 	 Within the last month 1-3 months ago 4-6 months ago More than 6 months ago 	 Less than one month More than or month
[Medicine]	[Condition]	YesNo	 Less than one month 1-3 months 4-6 months 7-12 months More than one year 	 Within the last month 1-3 months ago 4-6 months ago More than 6 months ago 	 Less than one month More than or month

21. Would you be comfortable discussing this medicine/these medicines in an interview?

Yes	→ ELIGIBLE
No	→ TERMINATE

Demographic Questions

22. What is the highest level of education you have completed?

- Less than high school diploma [Eligible for lower education groups]
- High school graduate or GED [Eligible for lower education groups]
- **G** Some college
- □ Technical or associates degree (2-year)
- 4-year degree
- Graduate or professional degree [RECRUIT NO MORE THAN 14% OF SAMPLE]

23. What type of health insurance do you currently have? [Accept multiple responses]

- Private insurance through an employer, group health plan, broker, agent, or Federal or state marketplace plan
- □ Medicaid or Medicare [RECRUIT 30% OF TOTAL SAMPLE NON-PRIVATE]
- Veterans Affairs, Tricare, or the Department of Defense [RECRUIT 30% OF TOTAL SAMPLE NON-PRIVATE]
- **Currently uninsured**
- Other [please specify]: ______

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24. What is your race? You may select more than one. [Accept multiple responses]

- □ White [RECRUIT NO MORE THAN 80% OF SAMPLE]
- **B**lack or African American
- Asian
- □ Native Hawaiian or Other Pacific Islander
- American Indian or Alaska Native

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

- □ Yes [RECRUIT 15% OF SAMPLE]
- 🗗 No

26. In which state do you live? [Display drop down list. Recruit at least 20% in each Census region.]

[drop down list of states]

27. What was your total household income before taxes during the past 12 months? Your response will be kept private.

- **\$30,000 or less [RECRUIT MINIMUM 20% OF SAMPLE < \$30,000]**
- **3** \$30,001 to \$65,000
- **5** \$65,001 to \$99,999
- **More than \$100,000**
- **D** Prefer not to answer

28. What is your sex?

- □ Male [RECRUIT AT LEAST 40% OF SAMPLE]
- Female [RECRUIT AT LEAST 40% OF SAMPLE]

Closing Scripts

Declined to Begin Screener

Thank you for your time.

Completed Screener

You have completed the online screener. One of our recruiters will be in touch if you qualify for this study. Thank you for your time.