[Display at bottom of Introduction screen]

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Biosimilars Patient Study

Phase 1 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 focus group about health-related materials for a specific type of medicine.

The groups will be led by a researcher through an online video platform. If you're eligible for the group, you can participate from home using a computer and web camera. The discussion will last about 90 minutes, and you will receive a \$75 honorarium once the sessions are finished and the project has concluded.

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		→ CONTINUE
	Under 18		→ TERMINATE
	years [Allow 1-99]		
2.	Have you ever worked? [Accept multiple responses.]		
	For a drug or pharmaceutical company		→ TERMINATE
	For a market research or marketing company, including RTI International or Survey Healthcare Globus		→ TERMINATE
	For the U.S. federal government (not including as a member of the military)		→ TERMINATE
	As a medical professional (such as a physician, nurse, or pharmacist)		→ TERMINATE
	None of the above		→ CONTINUE
3.	When was the last time you participated in an interview or a fo	cus group	for a research study?
	Within the past six months		→ TERMINATE
	More than six months ago		→ CONTINUE
	Never		→ CONTINUE

Yes				→ CONTINUE
No				→ TERMINATE
To participate in this study, you will need	_			
tablet or smartphone) and (2) a webcam	ı. Can you r	neet these req	uireme	ents?
Yes				→ CONTINUE
No				→ TERMINATE
During the focus group discussion, you wo	ng or speak	ng problems tl		
see the materials, hear the instructions, Yes	or comme	it on them?		→ TERMINATE
No			l	→ CONTINUE
Yes No			l I	→ CONTINUE → TERMINATE
Yes			J	→ CONTINUE
No			_	→ CONTINUE → TERMINATE
		althcare profesultiple respons	sional	→ TERMINATE
No The next questions are about your health any of the following medical conditions?	Accept m	althcare profesultiple respons → Ask Q10, t	ssional ses.] hen CO	→ TERMINATE ever diagnosed you
No The next questions are about your health any of the following medical conditions? kylosing spondylitis / Spondyloarthritis	? [Accept m	althcare profesultiple respons → Ask Q10, t → Ask Q10, t	essional ses.] hen Co	→ TERMINATE ever diagnosed you ONTINUE to Q15
No The next questions are about your healtlany of the following medical conditions? kylosing spondylitis / Spondyloarthritis priatic arthritis	C [Accept m	althcare profesultiple respons → Ask Q10, t → Ask Q10, t → Ask Q10, t	sional ses.] hen CC hen CC	→ TERMINATE ever diagnosed you ONTINUE to Q15 ONTINUE to Q15
No The next questions are about your healtl any of the following medical conditions? kylosing spondylitis / Spondyloarthritis priatic arthritis eumatoid arthritis	C [Accept m	althcare profesultiple respons → Ask Q10, t → Ask Q10, t → Ask Q10, t	ssional ses.] hen Co hen Co	→ TERMINATE ever diagnosed you ONTINUE to Q15 ONTINUE to Q15 ONTINUE to Q15
No The next questions are about your health any of the following medical conditions? kylosing spondylitis / Spondyloarthritis oriatic arthritis eumatoid arthritis ncer	C [Accept m	althcare profesultiple respons → Ask Q10, t → Ask Q10, t → Ask Q10, t → Ask Q10, t	hen CChen CC	→ TERMINATE ever diagnosed you DNTINUE to Q15 DNTINUE to Q15 DNTINUE to Q15 DNTINUE to Q15
No The next questions are about your health any of the following medical conditions? Exylosing spondylitis / Spondyloarthritis Periatic arthritis Beumatoid arthritis Incer Shn's disease	C [Accept m	althcare profesultiple respons → Ask Q10, t	hen CChen CChen CC	→ TERMINATE ever diagnosed you DNTINUE to Q15 DNTINUE to Q15 DNTINUE to Q15 DNTINUE to Q11 DNTINUE to Q15
No The next questions are about your health any of the following medical conditions? kylosing spondylitis / Spondyloarthritis priatic arthritis eumatoid arthritis ncer phn's disease erative colitis	P [Accept m	althcare profesultiple respons → Ask Q10, t → Ask Q10, t	hen CChen CChen CChen CChen CCChen CCC	→ TERMINATE ever diagnosed you ONTINUE to Q15 ONTINUE to Q15

Type 2 diabetes		→ Ask Q10, then	CONTINUE to Q13	
None of the above		→ SKIP to Q15		
10. How long ago were you diagnosed with respondent] [Allow 1-99 years and 0-1: years months (if less than 1 year)	-	i]? [Ask for each cor	ndition selected by	
11. Which type(s) of cancer were you diagr	nosed with?	? [Accept multiple re	esponses]	
Breast			→ CONTINUE	
Colorectal			→ CONTINUE	
Kidney			→ CONTINUE	
Leukemia			→ CONTINUE	
Lung			→ CONTINUE	
Lymphoma			→ CONTINUE	
Myeloma			→ CONTINUE	
Skin			→ CONTINUE	
Other (please specify)			→ CONTINUE	
12. Have you ever been diagnosed by a hear related side effect of chemot	-		ropenia , a blood-	
Yes			→ CONTINUE to Q15	
No			→ CONTINUE to Q15	
13. How long have you been using insulin t	o treat you	r diabetes?		
Less than one month			→ CONTINUE	
One month to less than one year			→ CONTINUE	
One year to less than three years			→ CONTINUE	
Three years or more			→ CONTINUE	
Not currently taking insulin			→ SKIP to Q15	
14. How often do you usually take insulin?				
Once per day or more		<u> </u>	→ CONTINUE to Q15	
Less than once per day			→ SKIP to Q15	
		L	*	

Yes, type 1 diabetes				→ CONTINUE
Yes, type 2 diabetes				→ CONTINUE
0				→ SEE Q20 INSTRUCTIONS
L6. What is this child's age?				
years [Allow 1-99]				
Age 18 or older		→ TERMINAT	E IF Q9=	None of the above
Under 18		→ CONTINUE		
making medication decisions, ac extremely involved	• .	. •		you are? → CONTINUE
making medication decisions, ac Extremely involved Frequently involved	• .	. •	you say	you are? → CONTINUE → CONTINUE
Extremely involved Frequently involved Somewhat involved	• .	. •	you say	you are? → CONTINUE → CONTINUE → SEE Q20 INSTRUCTIONS
making medication decisions, ac Extremely involved Frequently involved Somewhat involved Not at all involved	dministering i	nsulin)? Would	you say	you are? → CONTINUE → CONTINUE → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS
making medication decisions, active mely involved frequently involved from what involved Not at all involved	dministering i	nsulin)? Would	you say	you are? → CONTINUE → CONTINUE → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS
making medication decisions, active mely involved Frequently involved Somewhat involved Not at all involved 18. How long has your child been used in the more than one month	dministering i	nsulin)? Would	you say	you are? → CONTINUE → CONTINUE → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS es? → CONTINUE
making medication decisions, ac Extremely involved Frequently involved	dministering i	nsulin)? Would	you say	you are? → CONTINUE → CONTINUE → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS
making medication decisions, active mely involved requently involved somewhat involved Not at all involved labeled with the source of the sour	sing insulin to	nsulin)? Would	you say	you are? → CONTINUE → CONTINUE → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS es? → CONTINUE → SEE Q20 INSTRUCTIONS
making medication decisions, activate mely involved frequently involved for more than one month for less than one month for currently taking insulin 9. How often does your child take	sing insulin to	nsulin)? Would	diabete	you are? → CONTINUE → CONTINUE → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS es? → CONTINUE → SEE Q20 INSTRUCTIONS
making medication decisions, activated involved Frequently involved Frequently involved From at all involved For more than one month For less than one month Not currently taking insulin	sing insulin to	treat his or her	you say □ □ □ diabete □ □	you are? → CONTINUE → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS es? → CONTINUE → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS → SEE Q20 INSTRUCTIONS

- If individual's responses have checked only the green boxes, skip to Q25.
- If no yellow or green boxes selected, terminate and display closing script.]

20. These next questions ask about medications that you take for your health conditions. Have you ever taken one or more of the following medications to treat [display condition(s) based on responses to Q9 and Q11]?

[Display list of medications for each applicable medical condition.]

[Allow multiple responses. If one or more medications selected, continue to Q21. If no medications selected, terminate.]

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

List of Medications for Q20

Condition	Medications Brand Name [generic Name]
Ankylosing Spondylitis/ Spondyloarthritis	Amjevita [adalimumab-atto] (biosimilar) Cimzia [certolizumab] Cosentyx [secukinumab] Cyltezo [adalimumab-adbm] (biosimilar) Enbrel [etanercept] Erelzi [etenercept-szzs] (biosimilar) Eticovo [etanercept-ykro] (biosimilar) Hadlima [adalimumab-bwwd] (biosimilar) Humira [adalimumab] Hyrimoz [adalimumab-adaz] (biosimilar) Inflectra [infliximab-dyyb] (biosimilar) Ixifi [infliximab-qbtx] (biosimilar) Remicade [infliximab] Renflexis [infliximab-abda] (biosimilar) Simponi [golimumab] Taltz [xekixumab]
Psoriatic Arthritis	□ Amjevita [adalimumab-atto] (biosimilar) □ Cimzia [certolizumab] □ Cosentyx [secukinumab] □ Cyltezo [adalimumab-adbm] (biosimilar) □ Enbrel [etanercept] □ Erelzi [etenercept-szzs] (biosimilar) □ Hadlima [adalimumab-bwwd] (biosimilar) □ Humira [adalimumab] □ Hyrimoz [adalimumab-adaz] (biosimilar) □ Inflectra [infliximab-dyyb] (biosimilar) □ Ixifi [infliximab-qbtx] (biosimilar) □ Orencia [abatacept] □ Otezla [apremilast] □ Remicade [infliximab] □ Renflexis [infliximab-abda] (biosimilar) □ Simponi [golimumab] □ Simponi Aria [golimumab], IV Infusion □ Stelara [ustekinumab]

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	□ Taltz [xekixumab] □ Xeljanz [tofacitinib]
Rheumatoid Arthritis	Actemra [tocilizumab] Amjevita [adalimumab-atto] (biosimilar) Cimzia [certolizumab] Cosentyx [secukinumab] Cyltezo [adalimumab-adbm] (biosimilar) Enbrel [etanercept] Erelzi [etenercept-szzs] (biosimilar) Eticovo [etanercept-ykro] (biosimilar) Hadlima [adalimumab-bwwd] (biosimilar) Humira [adalimumab] Inflectra [infliximab-dyyb] (biosimilar) Ixifi [infliximab-qbtx] (biosimilar) Kevzara [sarilumab] Kineret [anakinra] Orencia [abatacept] Remicade [infliximab] Renflexis [infliximab-abda] (biosimilar) Rinvoq [upadacitinib] Rituxan [rituximab] Stelara [ustekinumab] Simponi [golimumab] Xeljanz [tofacitinib]
Cancer (leukemia)	Arzerra [ofatumumab] Asparlas [calaspargase pegol-mknl] Besponsa [inotuzumab ozogamicin] Blincyto [blinatumomab] Campath [alemtuzumab] Copiktra [duvelisib] Daurismo [glasdegib] Elspar [asparaginase] Erwinaze [asparaginase erwinia chrysanthemi] Gazyva [obinutuzumab) Intron A [interferon alfa-2b] Kymriah [tisagenlecleucel] Lumoxiti [moxetumomab pasudotox-tdfk] Mylotarg [gemtuzumab ozogamicin] Oncaspar [pegaspargase] Rituxan [rituximab] Rituxan Hycela [rituximab and hyaluronidase human] Ruxience [rituximab-abbs] (biosimilar) Truxima [rituximab-abbs] (biosimilar) Venclexta [venetoclax] Xospata [gilteritinib]

Cancer (blood - including lymphoma and myeloma)	Adcetris [brentuximab vedotin] Darzalex [daratumumab] Empliciti [elotuzumab] Erwinaze [asparaginase erwinia chrysanthemi] Gazyva [obinutuzumab] Keytruda [pembrolizumab] Kymriah [tisagenlecleucel] Ontak [denileukin diftitox] Rituxan [rituximab] Rituxan Hycela [rituximab and hyaluronidase human] Ruxience [rituximab-pvvr] (biosimilar) Truxima [rituximab-abbs] (biosimilar) Zevalin [ibritumomab tiuxetan]
Cancer (lung)	Avastin [bevacizumab] Bavencio [avelumab] Cyramza [ramucirumab] Imfinzi [durvalumab] Keytruda [pembrolizumab] Lorlatinib [lorlatinib] Mvasi [bevacizumab-awwb] (biosimilar) Opdivo [nivolumab] Portrazza [necitumumab] Tecentriq [atezolizumab] Vizimpro [dacomitinib]
Cancer (skin—melanoma, squamous cell carcinoma, basal cell carcinoma)	□ Alferon N [interferon alfa-n3] □ Braftovi [encorafenib] □ Keytruda [pembrolizumab] □ Libtayo [cemiplimab-ydhp] □ Opdivo [nivolumab] □ Mektovi [binimetinib] □ Proleukin [aldesleukin] □ Yervoy [ipilimumab]
Cancer (colorectal)	Avastin [bevacizumab] Cyramza [ramucirumab] Erbitux [cetuximab] Mvasi [bevacizumab-awwb] (biosimilar) Vectibix [panitumumab] Yervoy [ipilimumab] Zaltrap [ziv-aflibercept] Zirabev [bevacizumab-bvzr] (biosimilar)
Cancer (breast)	☐ Herceptin [trastuzumab] ☐ Herzuma [trastuzumab-pkrb] (biosimilar)

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	 □ Kadcyla [ado-trastuzumab emtansine] □ Kanjinti [trastuzumab-anns] (biosimilar) □ Ogivri [trastuzumab-dkst] (biosimilar) □ Ontruzant [trastuzumab-dttb] (biosimilar) □ Perjeta [pertuzumab] □ Talazoparib [talazaoparib] □ Tecentriq [atezolizumab] □ Trazimera [trastuzumab-qyyp] (biosimilar)
Cancer (kidney)	 Avastin [bevacizumab] Mvasi [bevacizumab-awwb] (biosimilar) Opdivo [nivolumab] Proleukin [aldesleukin] Yervoy [ipilimumab]
Cancer (other types)	Avastin [bevacizumab] Cyramza [ramucirumab] Elzonris [tagraxofusp-erz] Erbitux [cetuximab] Keytruda [pembrolizumab] Lartruvo [olaratumab] Lenvima [lenvatinib] Lynparza [olaparib] Mvasi [bevacizumab-awwb] (biosimilar) Poteligeo [mogamuliziumab] Tecentriq [atezolizumab]
Neutropenia (from cancer treatment)	□ Fulphila [pegfilgrastim-jmdb] (biosimilar) □ Granix [tbo-filgrastim] □ Neulasta [pegfilgrastim] □ Neupogen [filgrastim] □ Nivestym [filgrastim-aafi] (biosimilar) □ Udenyca [pegfilgrastim-cbqv] (biosimilar) □ Zarxio [filgrastim-sndz] (biosimilar)
Crohn's Disease	 □ Amjevita [adalimumab-atto] (biosimilar) □ Cimzia [certolizumab] □ Cyltezo [adalimumab-adbm] (biosimilar) □ Entyvio [vedolizumab] □ Hadlima [adalimumab-bwwd] (biosimilar) □ Humira [adalimumab] □ Hyrimoz [adalimumab-adaz] (biosimilar) □ Inflectra [infliximab-dyyb] (biosimilar) □ Ixifi [infliximab-qbtx] (biosimilar) □ Remicade [infliximab] □ Renflexis [infliximab-abda] (biosimilar)

		[ustekinumab] [natalizumab]	
Ulcerative Colitis	☐ Entyvio ☐ Hadlim ☐ Humira ☐ Hyrimo ☐ Inflectr ☐ Ixifi [Int ☐ Remica ☐ Renflex ☐ Simpor ☐ Stelara	[adalimumab-adbm] [vedolizumab] [a [adalimumab-bwwd] [adalimumab] [a [adalimumab-adaz] [a [infliximab-dyyb] (bi fliximab-qbtx] (biosimab [infliximab] [is [infliximab] [is [infliximab] [ustekinumab] [tofacitinib]] (biosimilar) (biosimilar) osimilar) ilar)
Eczema/Atopic Dermatitis	☐ Dupixe	nt [dupilumab]	
Psoriasis	Cimzia Cosent Cyltezo Enbrel Erelzi [a Eticovo Hadlim Humira Hyrimo Ilumya Inflectr Siliq [bi Skyrizi Stelara	ta [adalimumab-atto] [certolizumab] yx [secukinumab] [etanercept] etanercept-szzs] (biosi [etanercept-ykro] (bi a [adalimumab-bwwd [adalimumab] yz [adalimumab] yz [adalimumab] a [infliximab-dyyb] (bi fliximab-qbtx] (biosim [apremilast] ide [infliximab] xis [infliximab-abda] (bi rodalumb] [risankizumab] [ustekinumab] xekizumab] a [guselkumab]	(biosimilar) imilar) osimilar)] (biosimilar) (biosimilar) osimilar) iosimilar)
21. Are you currently taking [list bic medication]	logics selected ir	ı Q20, one at a time]? [Record response for each
Yes			→ CONTINUE
No			→ SKIP TO Q23 IF NO TO ALL MEDS

22. How long have you been taking [list biologics currently taking, one at a time]? [Record response for each medication]

	_	>		
Less than one month		→ TERMINATE		
One month to less than three months		→ CONTINUE to Q25		
Three months to less than six months		→ CONTINUE to Q25		
Six months to less than two years		→ CONTINUE to Q25		
Two years to less than five years		→ CONTINUE to Q25		
Five years or more		→ CONTINUE to Q25		
23. When did you last take [list biologics selected in Q20 that time]? [Record response for each medication]	_			
Within the last month		→ CONTINUE		
One month to less than three months ago		→ CONTINUE		
Three months to less than six months ago		→ CONTINUE		
Six months ago or more		→ TERMINATE		
at a time] when you were still using it? [Record response f		→ TERMINATE		
One month or longer		→ CONTINUE to Q25		
25. Would you be comfortable discussing these medications in Yes No	n a focus gr	→ ELIGIBLE → TERMINATE		
Demographic Questions				
26. What is the highest level of education that you have comp	oleted?			
 □ Less than high school diploma □ High school graduate or GED □ Technical or Associates degree (2-year) □ Some college but not a degree □ 4-year degree □ Graduate or professional degree [RECRUIT NO MORE THAN 14% OF SAMPLE] 				
27. What type of health insurance do you currently have? [Accept multiple responses]				
 □ Private insurance through an employer, group health plan, broker, or agent □ Private insurance through a 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]:	
28. What is your race? You may select more than one. [Accept multiple responses]			
		White [RECRUIT NO MORE THAN 80% OF SAMPLE] Black or African American Asian Native Hawaiian or Other Pacific Islander American Indian or Alaska Native	
29. Are you of Hispanic, Latino, or Spanish origin?			
		Yes [RECRUIT 15% OF SAMPLE] No	
30. In which state do you live? [Display drop down list. Recruit at least 20% in each Census region.]			
	[dro	op down list of states]	
31.		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] \$30,001 to \$65,000 \$65,001 to \$99,999 More than \$100,000 Prefer not to answer	
32.	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.