|  |
| --- |
| *[Display at bottom of Introduction screen]*  According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0695 and the expiration date is 02/28/2021. The time required to complete this information collection is estimated to average 5 minutes per response to answer the questions to determine eligibility. |

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]**

1. **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** |

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

|  |  |  |
| --- | --- | --- |
| Within the past six months | ❒ | 🡺 **TERMINATE** |
| More than six months ago | ❒ | 🡺 **CONTINUE** |
| Never | ❒ | 🡺 **CONTINUE** |

1. **Do you have high-speed Internet access at home? That is, are you able to stream video without any difficulty?**

|  |  |  |
| --- | --- | --- |
| Yes | ❒ | 🡺 **CONTINUE** |
| No | ❒ | 🡺 **TERMINATE** |

1. **To participate in this study, you will need two things: (1) a desktop or laptop computer (not just a tablet or smartphone) and (2) a webcam. Can you meet these requirements?**

|  |  |  |
| --- | --- | --- |
| Yes | ❒ | 🡺 **CONTINUE** |
| No | ❒ | 🡺 **TERMINATE** |

1. **During the focus group discussion, you will be asked to review written materials and offer your opinions. Do you have any vision, hearing or speaking problems that would affect your ability to see the materials, hear the instructions, or comment on them?**

|  |  |  |
| --- | --- | --- |
| Yes | ❒ | 🡺 **TERMINATE** |
| No | ❒ | 🡺 **CONTINUE** |

1. **Are you comfortable speaking and reading English independently and without an interpreter?**

|  |  |  |
| --- | --- | --- |
| Yes | ❒ | 🡺 **CONTINUE** |
| No | ❒ | 🡺 **TERMINATE** |

1. **For study purposes, the focus group will be audio and video recorded. Are you okay with being recorded and being visible on screen to a small number of research team members?**

|  |  |  |
| --- | --- | --- |
| Yes | ❒ | 🡺 **CONTINUE** |
| No | ❒ | 🡺 **TERMINATE** |

1. **The next questions are about your health. Has a healthcare professional ever diagnosed you with any of the following medical conditions? [Accept multiple responses.]**

|  |  |  |
| --- | --- | --- |
| Ankylosing spondylitis / Spondyloarthritis | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q15** |
| Psoriatic arthritis | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q15** |
| Rheumatoid arthritis | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q15** |
| Cancer | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q11** |
| Crohn’s disease | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q15** |
| Ulcerative colitis | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q15** |
| Eczema / Atopic dermatitis | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q15** |
| Psoriasis | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q15** |
| Type 1 diabetes | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q13** |
| Type 2 diabetes | ❒ | 🡺 **Ask Q10, then** **CONTINUE to Q13** |
| None of the above | ❒ | 🡺 **SKIP to Q15** |

1. **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) |

1. **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** |

1. **Have you ever been diagnosed by a healthcare professional with neutropenia, a blood-related side effect of chemotherapy?**

|  |  |  |
| --- | --- | --- |
| Yes | ❒ | 🡺 **CONTINUE to Q15** |
| No | ❒ | 🡺 **CONTINUE to Q15** |

1. **How long have you been using insulin to treat your 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** |

1. **How often do you usually take insulin?**

|  |  |  |
| --- | --- | --- |
| Once per day or more | ❒ | 🡺 **CONTINUE to Q15** |
| Less than once per day | ❒ | 🡺 **SKIP to Q15** |

1. **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 Q20 INSTRUCTIONS** |

1. **What is this child’s age?**

|  |
| --- |
| \_\_\_ years **[Allow 1–99]** |

|  |  |  |
| --- | --- | --- |
| Age 18 or older | ❒ | 🡺 **TERMINATE IF Q9=None of the above** |
| Under 18 | ❒ | 🡺 **CONTINUE** |

1. **How involved are you in managing your child’s diabetes (e.g., scheduling doctor’s appointments, making medication decisions, administering insulin)? Would you say you are...?**

|  |  |  |
| --- | --- | --- |
| Extremely involved | ❒ | 🡺 **CONTINUE** |
| Frequently involved | ❒ | 🡺 **CONTINUE** |
| Somewhat involved | ❒ | 🡺 **SEE Q20 INSTRUCTIONS** |
| Not at all involved | ❒ | 🡺 **SEE Q20 INSTRUCTIONS** |

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

|  |  |  |
| --- | --- | --- |
| For more than one month | ❒ | 🡺 **CONTINUE** |
| For less than one month | ❒ | 🡺 **SEE Q20 INSTRUCTIONS** |
| Not currently taking insulin | ❒ | 🡺 **SEE Q20 INSTRUCTIONS** |

1. **How often does your child take insulin?**

|  |  |  |
| --- | --- | --- |
| Once per day or more | ❒ | 🡺 **SEE SKIP PATTERN BELOW** |
| Less than once per day | ❒ | 🡺 **SEE SKIP PATTERN BELOW** |

**[Skip pattern:**

* + **If individual’s responses have checked one or more of the yellow boxes, proceed to Q20.**
  + **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.]**

1. **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) * Eticovo [etanercept-ykro] (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] * 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-pvvr] (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) * 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) * Stelara [ustekinumab] * Tysabri [natalizumab] |
| Ulcerative Colitis | * 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) * Simponi [golimumab] * Stelara [ustekinumab] * Xeljanz [tofacitinib] |
| Eczema/Atopic Dermatitis | * Dupixent [dupilumab] |
| Psoriasis | * Amjevita [adalimumab-atto] (biosimilar) * Cimzia [certolizumab] * Cosentyx [secukinumab] * Cyltezo [adalimumab-adbm] (biosimilar) * Enbrel [etanercept] * Erelzi [etanercept-szzs] (biosimilar) * Eticovo [etanercept-ykro] (biosimilar) * Hadlima [adalimumab-bwwd] (biosimilar) * Humira [adalimumab] * Hyrimoz [adalimumab-adaz] (biosimilar) * Ilumya [tildrakizumab] * Inflectra [infliximab-dyyb] (biosimilar) * Ixifi [infliximab-qbtx] (biosimilar) * Otezla [apremilast] * Remicade [infliximab] * Renflexis [infliximab-abda] (biosimilar) * Siliq [brodalumb] * Skyrizi [risankizumab] * Stelara [ustekinumab] * Taltz [lxekizumab] * Tremfya [guselkumab] |

1. **Are you currently taking [list biologics selected in Q20, one at a time]? [Record response for each medication]**

|  |  |  |
| --- | --- | --- |
| Yes | ❒ | 🡺 **CONTINUE** |
| No | ❒ | 🡺 **SKIP TO Q23 IF NO TO ALL MEDS** |

1. **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** |

1. **When did you last take [list biologics selected in Q20 that individual is not current taking, one at a 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** |

1. **How long did you take [list of biologics selected in Q20 that individual is not currently taking, one at a time] when you were still using it? [Record response for each medication]**

|  |  |  |
| --- | --- | --- |
| Less than one month | ❒ | 🡺 **TERMINATE** |
| One month or longer | ❒ | 🡺 **CONTINUE to Q25** |

1. **Would you be comfortable discussing these medications in a focus group?**

|  |  |  |
| --- | --- | --- |
| Yes | ❒ | 🡺 **ELIGIBLE** |
| No | ❒ | 🡺 **TERMINATE** |

**Demographic Questions**

1. **What is the highest level of education that you have completed?**

* 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]

1. **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]: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **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

1. **Are you of Hispanic, Latino, or Spanish origin?**

* Yes[RECRUIT 15% OF SAMPLE]
* No

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

[drop down list of states]

1. **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

1. **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.