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ONLINE SCREENER FOR PATIENT FOCUS GROUPS

INTRODUCTION

Thank you for your interest in participating in this focus group study sponsored by the U.S. Food and Drug Administration to better understand patient’s experiences, thoughts, and opinions about a specific type of medicine.

Each focus group will be led by a qualified researcher and will include between six and ten participants. The focus groups will be held online through screen-sharing and webcam video and will last about 90 minutes.

Please make sure to answer all of the following questions during this initial screening process to determine if you are eligible to participate in this study.

[Termination Language]

Thank you for your time. Unfortunately, you are not eligible to participate at this time.

- In the past five years up to today, have you or a member of your immediate family worked for any of the following types of organizations?

[Accept multiple responses]

A drug company	[]	> TERMINATE
A market research or marketing company	[]	> TERMINATE
A health care company or organization as a medical professional (such as a physician or nurse)	[]	> TERMINATE
U.S. Food and Drug Administration (FDA)	[]	> TERMINATE
National Institutes of Health (NIH)	[]	> TERMINATE
Centers for Medicare and Medicaid Services (CMS)	[]	> TERMINATE
Centers for Disease Control and Prevention (CDC)	[]	> TERMINATE
U.S. Department of Health and Human Services (HHS)	[]	> TERMINATE
None of the above	[]	> CONTINUE

2. When was the last time you participated in a research study, such as an interview or a group discussion?

Within the past three months	<input type="checkbox"/>	> TERMINATE
More than three months ago	<input type="checkbox"/>	> CONTINUE
Never	<input type="checkbox"/>	> CONTINUE

3. Have you been diagnosed with one or more of the following conditions? **[Accept multiple responses]**

Anemia	<input type="checkbox"/>	> CONTINUE to Q4
Ankylosing spondylitis/Spondyloarthritis	<input type="checkbox"/>	> CONTINUE to Q4
Cancer	<input type="checkbox"/>	> CONTINUE to Q3A
Crohn's disease	<input type="checkbox"/>	> CONTINUE to Q4
Eczema (also known as atopic dermatitis)	<input type="checkbox"/>	> CONTINUE to Q4
Glomerulonephritis	<input type="checkbox"/>	> CONTINUE to Q4
Hidradenitis suppurativa	<input type="checkbox"/>	> CONTINUE to Q4
Neutropenia associated with cancer treatment	<input type="checkbox"/>	> CONTINUE to Q4
Psoriasis	<input type="checkbox"/>	> CONTINUE to Q4
Psoriatic arthritis)	<input type="checkbox"/>	> CONTINUE to Q4
Rheumatoid arthritis	<input type="checkbox"/>	> CONTINUE to Q4
Ulcerative colitis	<input type="checkbox"/>	> CONTINUE to Q4
Vasculitis	<input type="checkbox"/>	> CONTINUE to Q4
None of the above	<input type="checkbox"/>	> TERMINATE

Brief descriptions of condition

[Programming Note: Insert descriptions as footnotes for Q3.]

<i>Condition</i>	<i>Description</i>
Anemia	A condition involving not having enough healthy red blood cells to carry adequate oxygen to body's tissues
Ankylosing spondylitis/Spondyloarthritis	Inflammatory disease that can cause vertebrae in the spine to fuse.

Cancer	A variety of conditions involving abnormal cell growth.
Crohn's disease	An inflammatory bowel disease involving inflammation of the digestive tract.
Glomerulonephritis	Inflammation of the tiny filters in the kidneys.
Eczema (also known as atopic dermatitis)	A skin condition involving itchy rashes.
Hidradenitis suppurativa	A chronic skin disease involving small, painful lumps under the skin.
Neutropenia associated with cancer treatment	Low white blood cell count associated with chemotherapy.
Psoriasis	A chronic skin condition involving cells building up rapidly on the surface of the skin, forming itchy and sometimes painful scaly red patches.
Psoriatic arthritis	A form of arthritis (which is an inflammatory joint condition) that affects some people who have psoriasis.
Rheumatoid arthritis	A chronic inflammatory disorder that can affect joints and other body systems.
Ulcerative colitis	An inflammatory bowel disease that affects the large intestine with inflammation and ulcers or sores.
Vasculitis (or more specifically systemic sclerosis vasculitis)	Inflammation of blood vessels that can affect one or more organs.

HARD QUOTAS:

Condition(s)	Number of Groups (Recruit 10 to seat 8 for each group)
Anemia	1
Arthritis (rheumatoid, psoriatic, ankylosing spondylitis/spondyloarthritis)	2
Cancer (including associated neutropenia)	2
Kidney conditions of glomerulonephritis and vasculitis	1
Skin conditions (psoriasis, hidradenitis suppurativa, or eczema/atopic dermatitis)	2
Inflammatory bowel disease (Crohn's disease or ulcerative colitis)	2

[Programming/Recruiter Note: If participant reports multiple medical conditions, please assign him/her to the group that has greater need for additional participants to fulfill quotas.]

3A. What type(s) of cancer have you been diagnosed with? **[Accept multiple responses]**

Breast	<input type="checkbox"/>	> CONTINUE
Colorectal	<input type="checkbox"/>	> CONTINUE
Kidney	<input type="checkbox"/>	> CONTINUE

Leukemia	<input type="checkbox"/>	> CONTINUE
Lung	<input type="checkbox"/>	> CONTINUE
Lymphoma	<input type="checkbox"/>	> CONTINUE
Myeloma	<input type="checkbox"/>	> CONTINUE
Skin	<input type="checkbox"/>	> CONTINUE
Other (please specify)	<input type="checkbox"/>	> CONTINUE

4. How long ago were you diagnosed with **[pipe in max of three condition(s) from Q3, one at a time]**?

Less than six months ago	<input type="checkbox"/>	> CONTINUE
Between six months and less than two years ago	<input type="checkbox"/>	> CONTINUE
Between two years and five years ago	<input type="checkbox"/>	> CONTINUE
More than five years ago	<input type="checkbox"/>	> CONTINUE

5. Have you taken any medicine to treat **[pipe in max of three condition(s) from Q3, one at a time]** in the past six months?

Yes	<input type="checkbox"/>	> CONTINUE
No	<input type="checkbox"/>	> TERMINATE
Don't know	<input type="checkbox"/>	> TERMINATE

6. Would you be comfortable discussing medicines you are taking for this/these conditions in a focus group?

Yes	<input type="checkbox"/>	> CONTINUE
No	<input type="checkbox"/>	> TERMINATE

7. What is your gender?

Female	<input type="checkbox"/>	> CONTINUE
Male	<input type="checkbox"/>	

8. Are you Hispanic or Latino?

Yes	<input type="checkbox"/>	> CONTINUE
No	<input type="checkbox"/>	

9. Which of the following best describes your race? You may choose one or

more categories. **[Accept multiple responses]**

White	<input type="checkbox"/>	> CONTINUE
Black or African American	<input type="checkbox"/>	
Asian	<input type="checkbox"/>	
American Indian or Alaska Native	<input type="checkbox"/>	
Native Hawaiian or Other Pacific Islander	<input type="checkbox"/>	

10. What is your age?

_____	<input type="checkbox"/>	> If <18, TERMINATE
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11. What state do you live in?

[Programming note: Display list of all states and DC; categorize into corresponding region based on response]

Northeast (CT, MA, ME, NH, NJ, NY, PA, RI, VT)	> CONTINUE
Midwest (IL, IN, IO, KS, MI, MN, MO, NE, ND, OH, SD, WI)	
West (AK, AZ, CA, CO, HI, ID, NM, MT, OR, UT, NV, WA, WY)	
South (AL, AR, DC, DE, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, WV)	

Thank you for taking the time to answer these questions. We will follow up with you with a phone call to ask a few additional questions to determine your eligibility to participate in this study.

PHONE SCREENER FOR PATIENT FOCUS GROUPS

Hello, my name is [Name], and I am calling from the research firm FieldGoals. I understand that you expressed interest in participating in a focus group study about a specific type of medicine by completing an initial online survey.

May I ask you a few additional questions to see if you are eligible to participate in the study?

Yes [CONTINUE]

No [THANK AND TERMINATE]

In this study, we will focus on biological products, which are also called biologics. Biological products are a type of medicine used to treat a variety of medical conditions. Some of my questions will be about the types of medicines you take, so please take a moment to look up your current prescriptions, if you need to.

There are no wrong answers to the questions I'm going to ask you. If an answer leads to me ending the call, it just means that you weren't eligible to participate based on the requirements for this specific study.

Next, I'm going to ask you about the medicines you have taken for (some of) the condition(s) you said you have.

[Termination Language]

Thank you for your time. Unfortunately, you are not eligible to participate at this time.

12. Have you ever taken one or more of the following biologics to treat **[pipe in max of three conditions, based on responses to Q3 and Q3A, one at a time]**? Please answer Yes, No, or Not Sure. **[Recruiter: READ LIST AND RECORD, accept multiple responses]**

[Pipe in list of corresponding biologics from the below table for each condition]

[Recruiter: If respondent states a preference to read the list of their medications to recruiter rather than having recruiter read the list, please adjust accordingly.]

[Recruiter: READ BRAND NAME AND RECORD, accept multiple responses. If respondent says "Yes" to five medications, proceed to Q13.]

If respondent does not respond "yes" to any of the listed biologics, then **THANK AND TERMINATE**

Drug Reference List for Q12

Anemia	Aranesp (AIR-uh-nesp) (darbepoetin alfa) Epogen (EE-po-jen) (epoetin alfa) Erythropoietin (err-ith-roh-POY-uh-tin) (EPO)
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	<p>Mircera (meer-SAIR-a) (methoxy polyethylene glycol-epoetin beta) Omontys (o-MON-tis) (peginesatide) Procrit (PROH-crit) (epoetin alfa) Retacrit (RET-a-crit) (epoetin alfa-epbx)</p>
Ankylosing spondylitis/ Spondyloarthritis	<p>Cimzia (SIM-zi-ah) (certolizumab) Cosentyx (coh-SEN-tix) (secukinumab) Enbrel (EN-brel) (Etanercept) Humira (hu-MEER-ah) (adalimumab) Inflectra (in-FLEC-tra) (infliximab-dyyb) Remicade (REM-i-cade) (infliximab) Renflexis (ren-FLEX-is) (infliximab-abda) Simponi (SIM-poh-nee) (golimumab)</p>
Cancer (leukemia)	<p>Arzerra (ar-ZAYR-uh) (ofatumumab) Asparlas (AS-par-las) (calaspargase pegol-mknl) Besponsa (beh-SPON-sa) (inotuzumab ozogamicin) Blincyto (blin-SY-toh) (blinatumomab) Campath (CAM-path) (alemtuzumab) Elspar (EL-spar) (asparaginase) Erwinaze (ER-wih-nayz) (asparaginase erwinia chrysanthemi) Gazyva (guh-ZY-vuh) (obinutuzumab) Intron A (IN-tron A) (interferon alfa-2b) Kymriah (kim-RAI-ah) (tisagenlecleucel) Lumoxiti (loo-MOX-i-tee) (moxetumomab pasudotox-tdfk) Mylotarg (MY-lo-targ) (gemtuzumab ozogamicin) Oncaspar (ON-kah-spar) (pegaspargase) Rituxan (rih-TUK-sun) (rituximab) Rituxan Hycela (rih-TUK-sun hy-SEL-ah) (rituximab and hyaluronidase human) Truxima (truk-SEE-muh) (rituximab-abbs)</p>
Cancer (blood – including lymphoma and myeloma)	<p>Adcetris (ad-SEH-tris) (brentuximab vedotin) Darzalex (DAR-zah-lex) (daratumumab) Emlipiti (em-PLIH-sih-tee) (elotuzumab) Erwinaze (ER-wih-nayz) (asparaginase erwinia chrysanthemi) Gazyva (guh-ZY-vuh) (obinutuzumab) Keytruda (kee-TROO-dah) (pembrolizumab) Kymriah (kim-RAI-ah) (tisagenlecleucel) Ontak (ON-tak) (denileukin diftitox) Rituxan (rih-TUK-sun) (rituximab) Rituxan Hycela (rih-TUK-sun hy-SEL-ah) (rituximab and hyaluronidase human) Truxima (truk-SEE-muh) (rituximab-abbs) Zevalin (ZEH-vuh-lin) (ibritumomab tiuxetan)</p>
Cancer (lung)	<p>Avastin (uh-VAS-tin) (bevacizumab) Bavencio (buh-VEN-see-oh) (avelumab)</p>

	<p>Cyramza (sy-RAM-zuh) (ramucirumab) Imfinzi (im-FIN-zee) (durvalumab) Keytruda (kee-TROO-dah) (pembrolizumab) Opdivo (op-DEE-voh) (nivolumab) Portrazza (por-TRA-zuh) (necitumumab) Tecentriq (teh-SEN-trik) (atezolizumab)</p>
<p>Cancer (skin— melanoma, squamous cell carcinoma, basal cell carcinoma)</p>	<p>Alferon N (interferon alfa-n3) Keytruda (kee-TROO-dah) (pembrolizumab) Libtayo (lib-TY-oh) (cemiplimab-ydhp) Opdivo (op-DEE-voh) (nivolumab) Proleukin (proh-LOO-kin) (aldesleukin) Yervoy (YER-voy) (ipilimumab)</p>
<p>Cancer (colorectal)</p>	<p>Avastin (uh-VAS-tin) (bevacizumab) Cyramza (sy-RAM-zuh) (ramucirumab) Erbitux (ER-bih-tux) (ceutximab) Vectibix (VEK-tih-bix) (panitumumab) Yervoy (YER-voy) (ipilimumab) Zaltrap (ZAL-trap) (ziv-aflibercept)</p>
<p>Cancer (breast)</p>	<p>Herceptin (her-SEPT-in) (trastuzumab) Kadcylla (kad-SY-luh) (ado-trastuzumab emtansine) Perjeta (per-JEH-tuh) (pertuzumab) Tecentriq (teh-SEN-trik) (atezolizumab)</p>
<p>Cancer (kidney)</p>	<p>Avastin (uh-VAS-tin) (bevacizumab) Opdivo (op-DEE-voh) (nivolumab) Proleukin (proh-LOO-kin) (aldesleukin) Yervoy (YER-voy) (ipilimumab)</p>
<p>Cancer (other types)</p>	<p>Avastin (uh-VAS-tin) (bevacizumab) Cyramza (sy-RAM-zuh) (ramucirumab) Erbitux (ER-bih-tux) (ceutximab) Keytruda (kee-TROO-dah) (pembrolizumab) Lartruvo (lar-TROO-voh) (olaratumab) Mvasi (muh-VAZ-ee) (bevacizumab-awwb)</p>
<p>Crohn's disease</p>	<p>Cimzia (SIM-zi-ah) (certolizumab) Entyvio (en-TIV-ee-oh) (vedolizumab) Humira (hu-MEER-ah) (adalimumab) Inflectra (in-FLEC-tra) (infliximab-dyyb) Renflexis (ren-FLEX-is) (infliximab-abda) Remicade (REM-i-cade) (infliximab) Simponi (SIM-poh-nee) (golimumab) Stelara (stuh-LAIR-ah) (ustekinumab) Tysabri (tai-SAB-ree) (natalizumab)</p>
<p>Eczema/Atopic Dermatitis</p>	<p>Dupixent (due-PIX-ent) (dupilumab)</p>
<p>Glomerulonephritis</p>	<p>Rituxan (rai-TUHX-in) (Rituximab)</p>

Hidradenitis suppurativa	Humira (hu-MEER-ah) (adalimumab)
Neutropenia (from cancer treatment)	Fulphila (FUL-fih-luh) (pegfilgrastim-jmdb) Granix (GRA-nix) (tbo-filgrastim) Neulasta (noo-LAST-ah) (pegfilgrastim) Neupogen (NOO-poh-jen) (filgrastim) Nivestym (NAI-vuh-stim) (filgrastim-aafi) Udenyca (yoo-den-i-kah) (pegfilgrastim-cbqv) Zarxio (ZAR-zee-oh) (filgrastim-sndz)
Psoriasis	Cimzia (SIM-zi-ah) (certolizumab) Cosentyx (koh-SEN-tix) (secukinumab) Enbrel (EN-brel) (etanercept) Humira (hu-MEER-ah) (adalimumab) Ilumya (ih-LOOM-ee-a) (tildrakizumab) Otezla (oh-TEZ-la) (apremilast) Remicade (REM-i-cade) (infliximab) Renflexis (ren-FLEX-is) (infliximab-abda) Stelara (stuh-LAIR-ah) (ustekinumab) Taltz (talltz) (Ixekizumab) Tremfya (trem-FAI-ah) (guselkumab) Siliq (sill-EEK) (Brodalumb)
Psoriatic Arthritis	Cimzia (SIM-zi-ah) (certolizumab) Cosentyx (koh-SEN-tix) (secukinumab) Humira (hu-MEER-ah) (adalimumab) Otezla (oh-TEZ-la) (apremilast) Remicade (REM-i-cade) (infliximab) Renflexis (ren-FLEX-is) (infliximab-abda) Simponi (SIM-poh-nee) (golimumab) Stelara (stuh-LAIR-ah) (ustekinumab) Taltz (talltz) (Ixekizumab) Xeljanz (ZEL-janz) (tofacitinib)
Rheumatoid arthritis	Actemra (ack-TEM-ra) (tocilizumab) Cimzia (SIM-zi-ah) (certolizumab) Cosentyx (koh-SEN-tix) (secukinumab) Enbrel (EN-brel) (etanercept) Humira (hu-MEER-ah) (adalimumab) Inflectra (in-FLEC-tra) (infliximab-dyyb) Kevzara (kev-ZAR-a) (sarilumab) Kineret (KIN-er-et) (Anakinra) Orencia (oh-REN-see-ah) (abatacept) Remicade (REM-i-cade) (infliximab) Renflexis (ren-FLEX-is) (infliximab-abda) Rituxan (rai-TUHX-in) (Rituximab) Stelara (stuh-LAIR-ah) (ustekinumab) Simponi (SIM-poh-nee) (golimumab) Xeljanz (ZEL-janz) (tofacitinib)

Ulcerative Colitis	Entyvio (en-TIV-ee-oh) (vedolizumab) Humira (hu-MEER-ah) (adalimumab) Inflixtra (in-FLEC-tra) (infliximab-dyyb) Remicade (REM-i-cade) (infliximab) Renflexis (ren-FLEX-is) (infliximab-abda) Stelara (stuh-LAIR-ah) (ustekinumab) Xeljanz (ZEL-janz) (tofacitinib)
Vasculitis	Rituxan (rai-TUHX-in) (rituximab)

13. When did you most recently take **[pipe in list of biologics taken from Q12, one at a time]**? **[Recruiter: DO NOT READ LIST]**

Within the last 30 days	<input type="checkbox"/>	> CONTINUE
Between one month and less than three months ago	<input type="checkbox"/>	> CONTINUE
Between three and less than six months ago	<input type="checkbox"/>	> CONTINUE
Six months ago or more	<input type="checkbox"/>	> TERMINATE if all drugs taken more than six months ago

14. For how long have you been taking (or for how long did you take) **[pipe in list of biologics taken from Q12, one at a time]**? **[Recruiter: DO NOT READ LIST]**

Less than 30 days	<input type="checkbox"/>	> TERMINATE if all drugs taken for less than one month
Between one month and less than three months	<input type="checkbox"/>	> CONTINUE
Between three months and less than six months	<input type="checkbox"/>	> CONTINUE
Between six months and less than two years	<input type="checkbox"/>	> CONTINUE
Between two years and five years	<input type="checkbox"/>	> CONTINUE
More than five years	<input type="checkbox"/>	> CONTINUE

[Recruiter: SCRIPT FOR INVITATION TO PARTICIPATE IN FOCUS GROUP]

I would like to verify that you have recently taken a biological product in the past six months. You stated that you have taken [**pipe in biologic(s) from Q12**] within the last six months, is that correct?

[If yes]: We would like to invite you to participate in a focus group. The focus group will take place online, and we will be asking you about your experiences and opinions about some of the medicines we asked about previously. We may ask for your feedback on some educational materials about these medicines. The focus group will be audio and video recorded, and project team members, including people from the FDA, may observe the discussion. Recordings and transcripts will not include your full name or any other personally identifiable information.

The focus group will last approximately 90 minutes, and you will receive \$75 as a token of appreciation, through either check or PayPal.

Your opinions are very important to us.

15. Are you interested in participating in this study?

Yes	<input type="checkbox"/>	> CONTINUE
No	<input type="checkbox"/>	> TERMINATE

16. The focus group will take place on DATE at TIME online. Will you be available to participate at this time?

Yes	<input type="checkbox"/>	> CONTINUE
No	<input type="checkbox"/>	> HOLD IN CASE SCHEDULE CHANGES

17. In order to participate in a focus group, we require that you have a **reliable internet connection and a webcam. You will also need to sign a consent form agreeing to participate and be video recorded during the discussion.** Will you be able to fulfill these requirements at the time of the discussion?

Yes	<input type="checkbox"/>	> CONTINUE
No	<input type="checkbox"/>	> TERMINATE

[Recruiter: Contact information is for recruitment purposes only and not to be delivered with screening information]

We will send you a confirmation email with instructions for the group. Could you please confirm your name, email address, and phone number? This information will

only be used to schedule you for the discussion. It will not be used in any recordings or reports.

Name: _____
Email: _____
Phone: _____

We strongly recommend that you have a list of your medications on hand when you participate in the focus group.

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 so we can find someone to take your spot. You can call us anytime at [PHONE #], and if we are not here, please leave a message and we will return your call.