

**FDA DOCUMENTATION FOR THE GENERIC CLEARANCE,
“TESTING COMMUNICATIONS ON DRUG PRODUCTS”
(0910-0695)**

TITLE OF INFORMATION COLLECTION: Studies to Enhance FDA Communications Addressing Biosimilar Drug Products: Focus Groups with Patients

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The primary purpose of this project is to conduct focus groups with patients to understand their knowledge, awareness, and attitudes related to biological products, including biosimilars, their experience communicating with healthcare professionals about these products, and what information needs they have with respect to these products. The secondary purpose is to gain feedback from patients on educational materials about biosimilars and/or interchangeable biological products. FDA will use the findings to inform enhancements to existing information resources and for the development of other communications about these products.

In 2010, President Obama signed into law The Patient Protection and Affordable Care Act, which amended the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be “biosimilar” to or “interchangeable” with an FDA-licensed biological product. FDA requires licensed biosimilar and interchangeable biological products to meet the agency’s rigorous standards for safety and efficacy. That means patients and health care professionals (HCP) will be able to rely upon the safety and effectiveness of the biosimilar or interchangeable product, just as they would the original reference product. Developing evidence-based communications about drug products can be challenging, especially when an entirely new type of drug product becomes available, as has happened recently with the introduction of biosimilar drug products to U.S. HCPs and patients.

2. Intended use of information:

FDA has determined that further research is needed to better understand how to most efficiently and effectively focus resources to educate and communicate to various stakeholder audiences, such as HCPs and consumers/patients, about biosimilars and interchangeable products and their safe and appropriate use. OMB approved FDA focus groups and interviews with HCPs on May 2, 2018. FDA now seeks approval to conduct patient focus groups as formative research to understand their knowledge, experiences, attitudes, decision-making, and information needs related to biosimilars.

FDA will use the results of this qualitative research to improve its understanding of patients’ needed and desired communications about biological drug products, including biosimilars, and to inform the revision of draft educational materials about these products and the development of new communications. The study results will help ensure that the messages and materials communicate key information that patients need and want about biosimilars and interchangeable products and address information that may be lacking or

misunderstood. FDA recognizes that the data collected will only be representative of the participants and will not be generalizable to the population segments characterized by the groups. The data will not be used for the purposes of making policy or regulatory decisions.

3. Description of respondents:

On behalf of FDA's Center for Drug Evaluation and Research (CDER), the research company Fors Marsh Group will conduct ten 90-minute online focus groups, each consisting of six to ten participants for a total of up to 80 participants. FMG will schedule 10 participants for each group with the goal of seating eight. FMG will conduct the groups with participants grouped into six segments of diagnosed medical conditions such that each group will include participants with similar medical conditions. All of the patients must be currently taking or have recently taken a biologic in the past six months. The medical conditions were selected because they are illnesses that are commonly treated with biologics.

- Anemia (one group)
- Kidney conditions – glomerulonephritis, vasculitis (one group)
- Arthritis – rheumatoid, psoriatic, ankylosing spondylitis/spondyloarthritis (two groups)
- Skin conditions – eczema/atopic dermatitis, psoriasis, hidradenitis suppurativa (two groups)
- Inflammatory bowel disease – Crohn's disease, ulcerative colitis (two groups)
- Cancer – various types: blood, lung, skin, breast, colorectal, and kidney and neutropenia (side effect of chemotherapy; two groups)

Focus group participants will be recruited by FieldGoals, a recruiting and market research firm with more than 50 years of experience in nationwide field data collection and consulting. FieldGoals has a database of 50,000 vetted consumers across the nation in urban, suburban, and rural geographies. The company's panel includes many different kinds of respondents for diverse projects across virtually all industries. For its many health-related research efforts, FieldGoals partners with several organizations (e.g., American Cancer Society, American Heart Association, American Medical Association) to maintain their pool of consumers with specific medical conditions and dispositions. For this study, FieldGoals will recruit individuals with diagnosed medical conditions from a participant pool that is diverse in terms of gender, age, race/ethnicity, education, and geography. Although the panel is large and diverse, it is not probability-based or ideal for some quantitative studies. Both because of relatively small sample size of this qualitative study and the limitations of the panel, the study results will only represent the enrolled participants and will not be generalizable to a larger population.

Recruiting will commence within two business days of the FDA project manager notifying FMG of approval by FDA's Institutional Review Board (IRB) and OMB. FieldGoals will take the following steps to recruit patients/consumers who are currently or have taken a biologic medicine in the past six months. First, they will recruit participants from their panel who live in various regions of the United States to ensure geographic diversity in the sample. The online nature of the focus groups also facilitates a wide geographic reach compared to focus groups conducted in person. Second, within

their participant panel, FieldGoals will start by targeting respondents diagnosed with illnesses that are sometimes treated with biologics, as outlined above. Initial targeting will be based on medical condition information that was previously collected about the panel members as part of their profile data. Outreach to additional potential participants will be expanded as needed. FieldGoals will initially reach out to potential participants within their panel via email to inform them that there is an upcoming study for which they may qualify (see Screener Invitation Email). Potential respondents will be able to click on a link in the email to answer a number of initial screening questions (see Online Screener). If respondents qualify after those initial screening questions, a recruiter will contact the respondents via phone to complete the remaining screening questions that are specific to biologic medicines they have taken, to determine eligibility, and to confirm their interest, availability, and ability to fulfill the requirements of being in the online focus group (see Phone Screener). If a respondent is qualified and selected for the study, the recruiter will schedule him or her over the phone. Recruiters will send out reminder scheduling emails (see Confirmation Email) and will make reminder phone calls. FocusVision, the online focus group platform provider, will send emails with log-in information for the group (see InterVu Respondent Invitation Template).

The focus group screener will ask participants questions about their general demographics (e.g., age, gender), diagnosed medical condition(s), and whether they are currently taking or have recently taken a biologic in the past six months (see Phone Screener). Respondents will be excluded if they have participated in a focus group or interview research in the last three months, or if they have worked for a health care company or organization as a medical professional, a drug company, a market research or marketing company, the FDA, National Institutes of Health (NIH), Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), or other parts of the U.S. Department of Health and Human Services (HHS). FMG will aim to recruit a mix of demographics to ensure adequate diversity in the sample.

4. Date(s) that the focus groups will be conducted and the location(s):

The patient focus groups will be conducted over a four-week period after OMB and FDA IRB approvals have been obtained.

5. How the information will be collected:

FMG will conduct 10 online focus groups with patients to understand their experiences, knowledge, their desired and needed information related to biological products, including biosimilars, and to gather their feedback on draft educational materials about biosimilar and/or interchangeable products created by the FDA. Each focus group will last 90 minutes and will consist of up to ten participants.

All focus groups will be conducted remotely via the FocusVision online platform, InterVu, which provides live, audio/video access for moderators and respondents in multiple locations to interact face-to-face. FocusVision InterVu is a secure, password-protected system. With the InterVu remote setup, members of the FDA team will be able to log in remotely and live stream each focus group, unobtrusively hearing the conversation and seeing what participants see in real time.

For each 90-minute focus group, a trained moderator will lead the discussion using a semi-structured moderator's guide that ensures consistency in major topics but allows flexibility in probing each group depending on the discussion (see the Patient Semi-Structured Focus Group Moderator's Guide).

During the focus groups, a notetaker will observe and document the major themes in each session. With the consent of participants, FMG will audio and video record each session, produce a written transcript of the discussion, and use the transcript to supplement the team's notes. The recruiting coordinators will provide the participants with \$75 via check or PayPal as a token of appreciation following each session (see Section 7).

6. Confidentiality of respondents:

As the focus groups will be remote, a consent form will be emailed to each participant at the time of recruitment and scheduling. Participants will electronically sign a programmed version of the consent form so that their typed signature is collected in FieldGoals' survey system (see Consent Form). No participants will be allowed to participate without a signed consent form.

The recruitment coordinator, FieldGoals, will store information obtained through the screening processes (see Online Screener and Phone) on a password-protected computer in order to invite respondents and send them reminder emails or to make reminder phone calls. Only the recruitment coordinators assigned specifically to this project will have access to this information. Once the screening and recruitment process is completed, the recruiting firm will provide FMG with the screening data for the participants, which will include first names and last initials, but no contact information. FMG will keep this information on a password-protected computer. FMG will securely share with the FDA weekly recruitment updates through FMG's SFTP (secure file transfer protocol); participant information will include first name and last initial along with screening information. FMG will delete the information at the completion of the project. FieldGoals will coordinate with the online focus group platform provider FocusVision to contact participants through email and/or phone and will assist them with setting up the software, testing it, and logging in to the group. Participant contact information will not be provided to the FDA.

At the beginning of each group, FMG will reiterate the information contained in the informed consent form that participants previously signed: participation is voluntary and they do not have to answer any questions they do not want to and can stop participating at any time. Participants will be instructed to use only their first names during the groups. FMG will also inform participants that no full names or any personally identifying information (PII) will be used in any notes, reports, or materials; that only anonymized information reported in aggregate will be provided to the FDA; and that their information will be kept private to the extent possible given the study methods. As is the case for in-person focus groups, online participants will be able to see the moderator and each other only while the focus group is being conducted, and participants will be asked not to share anything that is discussed during the group with anyone outside of the group.

FDA will not have the full names or any contact information for any of the participants. Therefore, there will be no link between the data collected and the participants' identities.

Recordings and electronic and written materials obtained during the focus groups will be stored on a password-protected server that will be accessible only to the research team. FMG will retain these files for three years and then delete them. The information will be kept in a secured fashion that will permit access only by authorized project staff. All PII will be removed from transcripts, audio/video files, reports, and all other materials before FMG provides the materials to the FDA. The FDA will store all study files and materials on password-protected computers for a period of five years. These confidentiality methods will be approved by the FDA's IRB prior to collecting any information.

7. Amount and justification for any proposed incentive:

FMG proposes an incentive amount of \$75 as a token of appreciation. This \$75 will be the total amount paid to individuals for participation in this study, and it is not in addition to any incentive that participants otherwise receive for being part of the FieldGoals panel (e.g., points, money). All focus group participants will receive their incentive after their participation is completed, and they can elect to be paid by FieldGoals through check or PayPal.

The proposed incentive amount is below market rate for an effort of this type. Recruiting firms and researchers determine market rates for research participation based on what other comparable studies in the field are offering and what rate will incentivize the required population to participate in the research. FieldGoals estimates that other studies being conducted with similar populations and levels of effort in this market at this time pay incentives of at least \$100. This estimate is based on participants spending approximately two hours of their time on this effort, which includes time for online and phone screening, 90 minutes per session, and the request to log in 15 minutes early to confirm technical operation. The Bureau of Labor Statistics (BLS) calculated that the average hourly wage of employees on private nonfarm payrolls in May 2019 is \$27.83.¹ At that hourly rate, compensation for two hours is approximately \$56. Additional factors requiring an incentive for this study that is higher than the BLS average hourly rate include:

- Participants are required to join the group from a quiet location where there are no distractions, which may require childcare or special accommodations during that time. BLS calculated in May 2018 that the average hourly wage of childcare workers is \$11.83, making the average cost of two hours of childcare \$24.²
- The focus groups will be conducted online and participants must have a computer and broadband internet to participate in the groups; participating will use approximately two hours of data on their internet plans.
- Each of the special medical conditions (e.g., cancer patients) constitutes a limited sub-category of the population with unique recruitment challenges. The incentive should demonstrate an appreciation and respect for the time and effort these unique patients give in talking to researchers, and acknowledge any hardships they may experience while participating in the focus groups (e.g., missed or postponed medical treatment, discomfort from pain or gastrointestinal issues, fatigue).
- Participants will be asked to disclose some personal medical information to the moderator and other participants during the group. Webcams will be used for these

¹ <https://www.bls.gov/news.release/empsit.t19.htm>

² <https://www.bls.gov/oes/2018/may/oes399011.htm>

groups, requiring participants' faces to be visible to the moderator and other group members. Participants can often be wary of being on camera in online groups like these, requiring a higher incentive to persuade them to participate.

Although the proposed incentive amount of \$75 is lower than market rate, it is consistent with what OMB approved several years ago for online focus group participants in prior CDER/OCOMM research. On June 20, 2016, under control number 0910-0695, OMB approved \$75 for online focus groups with general consumers, chronic pain patients using prescription opioids, and family or friends of people using prescription opioids for chronic pain. FMG anticipates a successful data collection using \$75 incentives, and that this amount will help ensure that respondents honor their commitment to participate in the focus groups.

In FMG's and other researchers' experiences, offering lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and result in longer recruiting time as well as higher overall project costs to the government (for which additional funding is not available). Nonmonetary incentives generally produce participation rates no better than the complete absence of any incentives.³ The consequences of an insufficient incentive include the following.

- Increased time and cost of recruitment due to lower response and sign-up levels, and/or the need to schedule additional groups to ensure the overall number of participants.
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants).
- Skewed participant demographics, with increased representation of participants with lower incomes and lower education levels.
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group. This incurs additional costs and puts additional burden on the recruited participants who have to reschedule their participation in the focus group.
- Delays to the project, which is already on a tight timeline to finish before the contract ends and before a follow-up project begins.

8. Questions of a sensitive nature:

Participants will be asked to identify their medical condition, but the focus of the discussions will be on their experiences with and thoughts about the biologic medicines they take to treat their condition. Participants will know about these topics in advance and will have the opportunity to decline to participate. Furthermore, the screener will include an item to confirm that participants feel comfortable discussing in a focus group the medicines they take. The focus group discussion questions will focus primarily on respondents' experiences taking and communicating with HCPs about biologics, their

³ See: Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly*, 57, 62-79; Dykema, J. et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin pregnancy risk assessment monitoring system. *Maternal and child health journal*, 16(4), 785-791; Singer, E., & Kulka, R. A. (2002). Paying respondents for survey participation. In: *Studies of welfare populations: Data collection and research issues*, 105-128.

knowledge of biologics, and the information they would want to have about biologics. All participants will be told that they may skip any question that they do not want to answer or may stop participating at any time. They will also be informed that their responses will not be tied to them individually.

9. Description of statistical methods (i.e., sample size and method of selection):

Qualitative methods in the form of human coding via the software program NVivo will be used to analyze the data from the focus groups.

Specifically, organizational coding schemes will be developed based on the verbatim transcripts of the focus groups. Two team members will then independently code 20% of the transcripts (two transcripts). Once reliability is established (i.e., kappa coefficient of > .70 for all double-coded transcripts), coders will complete coding the transcripts individually.

The resulting coded content will be used to facilitate a systematic, thematic review of the qualitative data. Our analysis procedure includes coding transcripts within nodes to extrapolate key themes and, as appropriate and necessary, using analytical features (e.g., text searches, word frequency, coding queries) within NVivo. These results will ultimately guide the research team’s efforts to identify insights and representative quotes, draw conclusions, make actionable recommendations, and complete its reporting.

BURDEN HOUR COMPUTATION (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Online Screening for Focus Groups (Patients)	1000	2 minutes (.03 hours)	33
Phone Screening for Focus Groups (Patients)	160	7 minutes (.12 hours)	19
Focus Group, 15 minute early log in and 90 minute session (Patients)	80	105 minutes (1.5 hours)	140
TOTAL			192

REQUESTED APPROVAL DATE: June, 2019

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