FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "TESTING COMMUNICATIONS ON DRUGS PRODUCTS" (0910-0695)

.

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

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of Need:**

   The purpose of this study is to conduct focus groups with patients and caregivers to obtain feedback on FDA-produced informational materials about biosimilars and interchangeable biologic products. FDA developed these materials to help patients and caregivers understand biosimilars and interchangeable biologics and to encourage them to ask their healthcare professionals (HCPs) if they have questions about these products. The feedback will help to ensure the materials meet audiences' information needs and will help FDA to strengthen the materials' relevance, trustworthiness, clarity, and usefulness prior to dissemination.

   Biologic medications are an increasingly popular and expensive treatment option in the United States. However, biologics are considerably more expensive than synthetic drugs, which can limit patient access and reduce adherence. One strategy intended to increase patient access to biologics and reduce costs is the introduction of biosimilar and interchangeable biologics. Unlike originator biologics, biosimilars are approved by the U.S. Food and Drug Administration (FDA) via an abbreviated licensure pathway based on analytical similarity data and selected clinical data.

   This study is an extension of related patient focus groups conducted in 2019, which OMB approved under control number 0910-0695 on June 17, 2019. The 2019 study was primarily exploratory, asking patients questions about their knowledge, awareness, and attitudes related to biologics, including biosimilars; their experience communicating with HCPs about these products; and their information needs with respect to these products. This 2020 study will gather patients' feedback on materials that were created using the findings from the previous study. These materials include the attached infographic and fact sheet, as well as four short videos.

2. **Intended Use of Information:**

   FDA will use the results of this qualitative research to revise the informational materials to ensure that they are understandable, relevant, and useful to patients and caregivers. The study results will ensure that the materials communicate key information around biosimilars and interchangeable biologic products and address any misperceptions about biosimilar products. 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.

In 2021, FDA plans to conduct additional one-on-one web-based interviews with the same target populations, though not the same participants. FDA will use these interviews to get individual reactions to the informational materials, obtain feedback on any modifications FDA makes to the materials based on the focus group findings, and help further refine the materials prior to dissemination. FDA will submit a separate information collection request for these one-on-one interviews after the 2020 focus groups have concluded.

3. Description of Respondents:

In collaboration with FDA's Center for Drug Evaluation and Research (CDER), RTI will conduct sixteen 90-minute, web-based focus groups (*n*=9 per group; *n*=144 total). The patient population for the study will be similar to that used in 2019 except for the addition of diabetic adults and caregivers of diabetic children since insulin is being reclassified as a biologic product and biosimilar versions may soon be on the market. Thus, RTI will conduct the groups with individuals who: (1) are currently taking, or have recently taken, a biologic; or (2) are the primary caregiver for a child who is currently taking, or has recently taken, insulin. Specifically, RTI will conduct the groups with six different audience segments:

- Inflammatory arthritis patients (3 groups)
- Cancer patients (3 groups)
- Inflammatory bowel disease patients (3 groups)
- Skin condition patients (3 groups)
- Diabetes patients (2 groups)
- Parents/Caregivers of children with diabetes (2 groups)

Survey Healthcare (SHC), a market research firm with a nationwide panel of more than 150,000 patients and caregivers, will recruit and screen participants. For this study, SHC will recruit individuals with diagnosed medical conditions from a robust participant pool that is diverse in terms of education, sex, age, race/ethnicity, geography, health insurance coverage, and household income. However, because of the relatively small sample size of this qualitative study, the results will only represent the enrolled participants and will not be generalizable to a larger population.

Recruitment will be conducted via email and phone. For email recruitment, SHC will send potential participants an email (see Study Invitation) explaining the study and inviting them to complete a brief online screener. Potential respondents will be able to click on a link in the email to answer a number of initial screening questions (see Web Screener). Individuals who are interested and appear to qualify will be contacted by phone to verify their responses and schedule their participation in a focus group (see Confirmation Script). For telephone recruitment, SHC will call potential participants, screen them for eligibility, and—if eligible—schedule them for a focus group (see Phone Screener). SHC will schedule focus groups on days and times that are most likely to be convenient for participants, likely weekdays early in the morning (6:00–8:00 am) and evenings (6:00–10:00 pm), to accommodate participants' work schedules.

Respondents will be excluded if they have participated in a focus group or interview research in the past six months, if they have vision or hearing problems that would prevent them from commenting on the informational materials, or if they are currently employed by the federal government, a pharmaceutical company, a research company, or in the healthcare field.

4. Date(s) to be Conducted:

Given the ongoing COVID-19 pandemic, the online focus groups will be conducted after receipt of OMB approval and when the U.S. infection rate slows.

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

5. How the Information Is Being Collected:

RTI will conduct the focus groups online using FocusVision Intervu, a video and audio platform designed specifically for qualitative research. FocusVision InterVu is a secure, password-protected system.

For each 90-minute focus group, a trained moderator will lead the discussion from his or her computer, and a separate note-taker and logistics coordinator will assist. Once connected, the participants and moderator will be able to see one another on screen, and the moderator will be able to share materials through screen sharing. The moderator will lead the discussion using a semi-structured moderator guide that ensures consistency in major topics but allows flexibility in probing each group depending on the discussion (see Moderator Guide). FDA staff will be able to observe unobtrusively and will not be visible on screen.

During the focus groups, a note-taker will observe and document the major themes in each session. With the consent of participants, we will audio record each session, produce a written transcript of the discussion, and use the transcript to supplement the team's notes. SHC will provide participants with $75 via third party payment providers, such as TangoCard or PayPal, as a token of appreciation following the completion of all of the sessions (see Section 7).

6. Confidentiality of Respondents:

Because the focus groups will be conducted online, SHC will email each participant a link to an online consent form at the time of recruitment and scheduling (see Advance Email). Participants will electronically sign a programmed version of the consent form so that a date/time stamp of consent is collected in SHC's survey system (see Consent Form). After participants electronically sign the form, SHC will email each participant a downloadable copy of their form for their records. No participants will be allowed to participate without a signed consent form.

SHC will store screening and consent data on a password-protected computer in order to invite respondents and send them reminder emails and phone calls the day before their scheduled focus group. Only SHC staff assigned specifically to this project will have access to this information. Once the screening and recruitment process is complete, SHC will provide RTI with the screening data for the participants, which will include first names and last initials, but no full names, contact information, or other personally identifying information (PII).

SHC will coordinate with the online platform provider (FocusVision) to contact participants and assist them with setting up the InterVu software, testing it, and logging in to the group. Participant contact information will not be provided to the FDA or RTI.

At the beginning of each group, RTI will reiterate the information contained in the informed consent that participants previously signed (i.e., 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. RTI will also inform participants that no full names or any 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 secure to the extent permitted by law. As is the case for in-person focus groups, online participants will be able to see the moderator and one another 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 and RTI will not have the full names, contact information, or PII 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. RTI will retain these files for 10 years and then delete them. The information will be kept in a secured fashion that will permit access only by authorized project staff. RTI will check all transcripts, audio/video files, reports, and other materials for PII before providing them to the FDA. The FDA will store all study files and materials on password-protected computers for a period of 10 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

We propose 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 SHC panel (e.g., points, money). All focus group participants will receive their incentive after all focus groups have been completed, and they can elect to be paid by SHC through PayPal, TangoCard, or similar vendors.

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. SHC and other vendors estimate that other studies being conducted with similar populations and levels of effort in this market at this time pay incentives of $100-$150. This estimate is based on participants spending approximately two hours of their time on this effort, which includes time for online and phone screening (5 minutes), time for testing the platform (10 minutes), time to participate in the focus group (90 minutes), 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 (Bureau of Labor Statistics, 2019). 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 (Bureau of Labor Statistics, 2018)
- 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, and many participants are likely to have significant medical issues. 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 other symptoms, 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 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 in recent years for online focus group participants in prior CDER/OCOMM research. Under control number 0910-0695, OMB has previously allowed $75 incentives for online focus groups about biosimilars using nearly the same patient population as this study (approved June 17, 2019) and 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 (approved June 20, 2016). RTI 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 RTI's and other researchers' experiences, offering lower or nonmonetary incentives will necessitate over-recruitment by higher percentages and may 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 (Church, 1993). The consequences of an insufficient incentive include the following:

- Increased time and cost of recruitment due to lower response and enrollment levels, and/or the need to schedule additional groups to achieve 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.

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 familiarity with biologic medicines and their impressions of the informational materials. 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. 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

We do not plan to use formal statistical methods in this study but rather qualitative analysis methods using NVivo 12 software. Specifically, we will obtain verbatim transcripts of the sessions based on the audio recordings and develop organizational coding schemes. Two team members will then calculate intercoder reliability across four double-coded transcripts. Once reliability is established (i.e., kappa coefficient of > .70), the two team members will split up and independently code the remaining 12 transcripts, and then conduct thematic analysis.

At this point, the research team will note regularities, patterns, and other explanations in the data (Gale et al., 2013; Miles & Huberman, 1994). This analytic approach will allow us to determine what knowledge, attitudes, perceptions, and decision processes are consistent across participants and to identify whether any of these elements differ by audience segment or other factors.

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	240	5 minutes	20
Phone Screening for Focus Groups	240	5 minutes	20
Focus Group, (Patients)	144	105 minutes (15 minute early log in and 90 minute session)	252
TOTAL			292

REQUESTED APPROVAL DATE: April 2020

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