

**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 and Caregiver Interviews

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of Need:

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 biological products. 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.

The purpose of this study is to conduct one-on-one interviews with patients and caregivers to obtain feedback on revised informational materials (produced by FDA) about biosimilar biological products. These materials include the attached infographic and fact sheets, as well as a short [video](#). FDA developed these materials to help patients and caregivers understand biosimilars and to encourage them to ask their healthcare professionals (HCPs) if they have questions about these products.

These interviews are an extension of related focus groups conducted with the same target populations in 2020, which OMB approved under control number 0910-0695 on April 9, 2020. The earlier focus groups were used to inform revisions to the materials. The feedback gathered in these interviews will help to further ensure the materials meet audiences’ information needs and will help FDA to strengthen the materials’ relevance, trustworthiness, clarity, and usefulness prior to dissemination.

2. Intended Use of Information:

FDA will use the results of this qualitative research to understand individual reactions to the informational materials, obtain feedback on modifications FDA made to the materials based on findings from the 2020 focus groups, and help further refine the materials prior to dissemination. The study results will ensure that the materials communicate key information around biosimilars and address any misperceptions about them. 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 interviews. The data will not be used for the purposes of making policy or regulatory decisions.

3. Description of Respondents:

In collaboration with FDA’s Center for Drug Evaluation and Research (CDER), RTI will conduct thirty 90-minute, web-based individual interviews. Participants will include

individuals who: (1) are currently or have recently taken a biologic; or (2) are the primary caregiver for a child who is currently taking insulin. The patient population for this study will be identical to that used in the 2020 focus groups, however interview participants will be different than those who participated in the focus groups. Specifically, RTI will conduct the interviews with six different audience segments:

- Inflammatory arthritis patients (6 interviews)
- Cancer patients (6 interviews)
- Inflammatory bowel disease patients (6 interviews)
- Skin condition patients (6 interviews)
- Diabetes patients (3 interviews)
- Parents/Caregivers of children with diabetes (3 interviews)

L&E Research, a nationwide market research firm, will recruit and screen participants. For this study, L&E 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, L&E will send potential participants an email (see Study Invitation) introducing the study and inviting them to complete a brief online screener. Potential participants 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 an interview (see Confirmation Script). For telephone recruitment, L&E will call potential participants, screen them for eligibility, and—if eligible—schedule them for an interview (see Phone Screener). L&E will schedule interviews on days and times that are most likely to be convenient for participants, likely weekdays in the early mornings (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 in the past six months, if they participated in the related 2020 focus groups, 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:

The interviews will be conducted during a six-week period after OMB and FDA IRB approvals have been obtained. The estimated timeframe for the interviews is July and August 2021.

5. How the Information Is Being Collected:

RTI will conduct the interviews online using Zoom, a web-based video and audio platform. Interviews will be conducted using a secure, password-protected Zoom meeting.

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

During the interviews, 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. L&E will provide participants with a \$75 honorarium as a token of appreciation (see Section 7). Specific instructions for obtaining the honorarium will be sent to participants' email addresses within one business day after the interview concludes. Participants will have the option to choose between a physical gift card or an electronic gift card that can be used at multiple online vendors.

6. Confidentiality of Respondents:

Because the interviews will be conducted online, L&E will send each participant a link to an electronic informed 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 L&E's system (see Consent Form). After participants electronically sign the form, L&E 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.

L&E 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 interview. Only L&E staff assigned specifically to this project will have access to this information. Once the screening and recruitment process is complete, L&E 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).

At the beginning of each interview, 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 interviews. 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.

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 interviews 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 L&E panel (e.g., points, money). All interview participants will receive their incentive from L&E as an electronic gift card after completing an interview.

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. L&E 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-\$125. This estimate is based on participants spending almost 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 interview (90 minutes), and the request to log in 10 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 2021 is \$30.33 (Bureau of Labor Statistics, 2021). At that hourly rate, compensation for two hours is approximately \$61. Additional factors requiring an incentive for this study that is higher than the BLS average hourly rate include:

- Participants are required to join the interview from a quiet location where there are no distractions, which may require childcare or special accommodations during that time. BLS calculated in May 2020 that the average hourly wage of childcare workers is \$12.88, making the average cost of two hours of childcare \$26 (Bureau of Labor Statistics, 2020)
- The interviews will be conducted online and participants must have a computer and broadband Internet to participate in the interviews; 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 interviews (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 interviewer during the session. Webcams will be used for these interviews, requiring participants' faces to be visible to the interviewer. Participants can often be wary of being on camera in online interviews 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 interview participants in prior CDER/OCOMM research. Under control number 0910-0695, OMB has previously allowed \$75 incentives for 90-minute online focus groups about biosimilars using the same patient population as this study (approved April 9, 2020). RTI anticipates successful data collection using \$75 incentives and anticipates this amount will help ensure that respondents honor their commitment to participate in the interviews.

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 interviews to achieve the overall number of participants.
- Skewed participant demographics, with increased representation of participants with lower incomes and lower education levels.
- Increased probability that an interview may need to be cancelled or postponed due to participants who do not show up as scheduled. This incurs additional costs and puts additional burden on participants.
- 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 discussion will largely focus 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 an interview 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 six

double-coded transcripts. Once reliability is established (i.e., kappa coefficient of > .80), the two team members will split up and independently code the remaining 24 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 Interviews	90	5 minutes	7.5
Phone Screening for Interviews	90	5 minutes	7.5
Interview	30	100 minutes (10 minute early log in and 90 minute session)	50
TOTAL			65

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