

**FDA DOCUMENTATION FOR THE GENERIC CLEARANCE
OF COMMUNICATION TESTING FOR DRUG PRODUCTS (0910-0695)**

TITLE OF INFORMATION COLLECTION: Healthcare Professional Interviews:
Data Disclosures in Communications about Prescription Drugs

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

Pharmaceutical firms may choose to disseminate publications to healthcare professionals that include data on unapproved uses of approved products that are not contained in FDA-approved labeling. At the same time, published data that are not supportive of what is presented in the information disseminated by the pharmaceutical firm may also exist. The *Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices* revised draft guidance (2014)¹, recommends that information such as reprints, clinical practice guidelines, and textbooks that discuss unapproved uses of approved drug products be disseminated with a representative publication that reaches contrary or different conclusions, when such information exists. Similarly, the *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* draft guidance (2011)² recommends that when conclusions of articles or texts that are disseminated in response to an unsolicited request have been specifically called into question by other articles or texts, a firm should disseminate representative publications that reach contrary or different conclusions regarding the use at issue.

The Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER), in collaboration with Westat, is conducting research on how healthcare professionals (HCP) process information about unapproved new uses of approved prescription drugs when made aware of other unsupportive information and evaluate the effectiveness of various disclosure approaches for this information.

2. Intended use of information:

We will use the results of this research to: (1) better understand how HCPs process this information about prescription drugs; (2) examine the utility and effectiveness of various approaches to the disclosure of unsupportive data; and (3) inform future quantitative phases of this research project.

3. Description of respondents:

This study phase will consist of 70 individual, in-depth interviews with HCPs who have prescribing authority. General inclusion and exclusion requirements built into the

1 *Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices - Revised Guidance* (2014). <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf>

2 *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices Draft Guidance* (2011). <https://www.fda.gov/media/82660/download>

screening protocol will ensure that all HCPs are currently practicing, spend at least half of their time on direct patient care, write at least 50 prescriptions per week and have not recently participated in market research. We will exclude HCPs who work in the marketing, advertising, or pharmaceutical industries or those who work for the Department of Health and Human Services because they may have specialized knowledge of FDA regulatory policies.

Prescriber Type

Two different HCP groups will be interviewed for this study: primary care physicians (PCP) and specialists (oncologists). We will recruit 35 participants from each of these two groups for a total of 70 HCP participants.

Demographics

Within each HCP group, we will aim to recruit individuals with diverse demographic characteristics (e.g., age, gender, race/ethnicity) to ensure that we hear from individuals with different backgrounds and perspectives.

4. Date(s) to be conducted and location(s):

We plan to conduct interviews between November 2019 and January 2020.

5. How the Information is being collected:

Recruitment Procedures

Oncologists. Westat will work with Reckner Healthcare to recruit oncologists for interviews. Reckner will draw a sample from their opt-in panel using stratified random sampling and estimates they will need to screen approximately 70 HCPs to recruit 35 qualified oncologists to the study. HCPs in the selected sample will initially be sent a recruitment email about the study and asked to complete an online screener to determine their eligibility for the study. After completing the screener, oncologists deemed eligible will be invited to participate in the interview. Those who agree to participate will be contacted by Reckner staff by phone to schedule the interview date/time and will also be rescreened to verify eligibility. Eligible oncologists who complete the interview will be offered \$275 as a token of appreciation. A copy of the recruitment email, screener, and interview invitation for eligible oncologists is included in Appendix A.

PCPs. Westat will work with SERMO to recruit PCPs. Similar to Reckner, SERMO will send a recruitment email about the study to a sample of their panel members and ask them to complete an online screener. Eligible PCPs will be invited to participate in the study, and those who agree will be contacted by SERMO's staff by phone to schedule the interview and will be rescreened. SERMO expects they will need to screen approximately 70 PCPs to recruit 35 eligible PCPs for the study. Eligible PCPs who complete the interview will be offered \$200 a token of appreciation. A copy of the introductory email, screener, and interview invitation for eligible PCPs is included in Appendix B.

Inclusion criteria for both HCP groups include:

- Practicing oncologist or PCP
- Writes 50 or more prescriptions per week
- Spends at least half of their time in direct patient care
- Access to a computer and high-speed Internet for interview
- Willingness to have interview recorded

Exclusion criteria for both HCP groups include:

- Works in marketing, advertising, or the pharmaceutical industry
- Works for the Department of Health and Human Services
- Participated in a focus group or interview-based research within previous 3 months

Once the interview has been scheduled by phone, a confirmation email letter will be sent to the recruited HCP (Appendix C) outlining the overall purpose of the research, confirming the date and time for the interview, and providing the link to the WebEx for the interview. An informed consent document (see Appendix D) will also be attached to the confirmation email letter.

Reckner and SERMO will send recruited HCPs' first names and scheduled interview dates to Westat. Westat will provide periodic updates about scheduled interviews to FDA. Two days prior to the scheduled interview, recruited HCPs will be sent a reminder email and offered an opportunity to decline participation, if they choose (Appendix E).

Data Collection Procedures

Data collection will be conducted remotely using WebEx. Trained interviewers from Westat will conduct individual in-depth interviews with the two HCP groups. Prior to starting interviews, interviewers will review the informed consent document sent to HCP participants (*sent in advance with the confirmation email letter*) and request their verbal consent to participate in the study and record the interview.

Using a semi-structured guide (Appendix F), the interviewer will ask HCP participants to describe how they learned about unapproved uses of approved prescription drugs, how unsupportive data affects their understanding and interpretation of the data and conclusions described in the unapproved use publication, and ways in which disclosures about the unsupportive data could be worded. No sensitive questions will be asked of HCP participants. The expected length of each interview is approximately 60 minutes.

Westat will audio record all interview sessions as well as provide remote login in order to allow FDA and Westat study staff to observe the sessions live. Observers will be muted once they log into the session, and thus only the Westat interviewer will be able to interact with the participant.

Westat will comply with safeguards for ensuring participant information is kept secure to the extent permitted by law. The last names of the participants will not appear on any

materials. Verbatim quotes included in the final report will not be attributed to any individual.

6. Confidentiality of Respondents:

Assurance of Privacy Provided to Participants

Recruited HCPs will receive an informed consent document (Appendix D) in advance of the interview. The document explains the study's purpose, participant rights, benefits and risks (minimal) of the study, and provides them with a contact name, email, and phone number should they have questions about the study. The document also notifies participants that interviews will be audio recorded and observers will be viewing the interviews remotely.

The interviewer will review the key elements of the informed consent document (e.g., study purpose, participant rights, potential risks and benefits, presence of observers) with HCP participants at the beginning of the interview. HCP participants will then be asked to provide their verbal consent to participate in the study and record the interview. In the event verbal consent for the audio recording is not given, the interview will not proceed and efforts will be made to schedule a replacement interview.

All data will be collected with an assurance that responses will remain private to the extent allowable by law. Both the informed consent document and the interview guide contain a statement emphasizing that no one will be able to link a participant's identity to his or her responses. Interviewers will not ask participants to provide identifying information beyond their first names. In addition, any quotations used in a report will not be linked to individual respondents. Further, no identifying information will be included in the data files delivered by Westat to FDA.

All interviews will be audio recorded for reporting purposes and will be livestreamed for observers. Both livestreamed and recorded interviews will only be viewed by FDA and Westat project staff. Livestreaming connections will be secure, using industry-standard firewalls and security practices. All data will be encrypted in transit using HTTPS. All equipment will be operated and maintained according to industry-standard practices, and all software validated using industry-standard quality assurance practices. Audio recordings will be used to create transcriptions of the interview sessions for reporting purposes and destroyed within three years after project completion.

After data collection is completed, Westat will provide FDA with copies of transcripts of all audio recorded interviews. These transcripts will be provided to FDA as a written record of the sessions. To ensure participant privacy, all PII other than first names will be redacted from the transcripts before delivery to FDA.

Record Keeping and Confidentiality

The following procedures will be used to ensure participant confidentiality before, during, and after fielding:

1. Reckner Healthcare and SERMO will recruit and schedule participants from their respective opted-in panels. Only first names of participants that have been scheduled for interviews will be provided to Westat. Any interview materials Westat shares with FDA will only contain participants' first names and whether they are a PCP or an oncologist.
2. During the interviews, participants will be addressed only by their first names. Any PII (beyond the first name) shared during the interview will be redacted from transcripts.
3. Respondent quotes used in reports will not be associated with any names or attributed to specific participants.

Contractors will not share personal information regarding participants with any third party without participants' permission unless it is required by law to protect their rights or to comply with judicial proceedings, court orders, or other legal processes. This possibility will be disclosed in the informed consent document.

All identifying information, including information collected during screening, will be kept on a separate password-protected computer and/or in locked cabinets for a period of no longer than three years after the project is complete, after which they will be destroyed by securely shredding documents or permanently deleting electronic information. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

All data will also be maintained in consistency with the FDA Privacy Act & Applicable System of Records Notices #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

7. Amount and justification for any proposed incentive:

Historically, physicians are one of the most difficult populations to survey, partly because of the demands on their professional time. Consequently, incentives assume an even greater importance with this group. Several studies (e.g., Refs. 1-3) have discussed the challenges of conducting research with HCPs and have concluded that offering substantial incentives is necessary to attain high response rates.

Recruiting physicians to participate in research has been shown to be difficult for reasons related primarily to the time burden (Ref. 4). Physicians' time is limited and, thus, quite valuable. Cash incentives, rather than nonmonetary gifts or lottery entries, can help improve response rates and survey completion rates (Refs. 5-8). A meta-analysis on methodologies for improving response rates in physician surveys examined 21 studies published between 1981 and 2006 that investigated the effect of monetary incentives on response rates in surveys of physicians. The authors found that the odds of responding to a survey with an incentive were 2.13 times greater than responding to a survey without incentives (Ref. 9). Martins and colleagues conducted a review of published oncology-focused studies to investigate methods for improving response rates. Their meta-analysis also showed that monetary incentives were effective at increasing response rates (Ref. 10). Previous research also suggests that providing incentives may help reduce sampling bias by increasing rates among individuals who are typically less likely to participate in

research (such as PCPs or physician specialists, e.g., Refs. 11-12) and ensuring participation from a cross section of physicians, which will improve data quality by improving validity and reliability.

In the current study, we will offer incentives in the amount of \$200 for PCPs and \$275 for oncologists for one hour of interview time. The proposed incentive amounts are below typical market incentive rates. Although market incentive rates for physicians are approximately \$250 to \$350 for similar research activities, with higher rates for specialists, the flexibility that our interview methodology affords— remote interviews in which physicians can participate from their offices and conducted around their schedules —helps offset the lower token of appreciation.

When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation. The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular study, we are asking HCPs to provide thought-intensive, open-ended feedback on materials that require a high level of engagement.

To address below-market incentive rates and ensure successful recruitment and fielding, Westat will coordinate closely with FDA to monitor recruitment status. Additionally, we will ensure that other considerations are in place to increase the likelihood of participation, such as:

1. Ensuring an adequate recruiting period before the start of fielding (as well as ongoing recruiting, as needed, during fielding period);
2. Availability of sessions at time slots that, in our experience, have been popular among HCPs—for example, early morning, evenings, lunch; and
3. Having the flexibility and appropriate staff available to run concurrent sessions to leverage popular session times.

8. Questions of a Sensitive Nature:

None.

9. Description of Statistical Methods (i.e. Sample Size & Method of Selection):

Statistical methods to recruit representative samples will not be used in this study. This study employs qualitative methods and uses convenience samples. HCP participants will be recruited from opt-in panels using a screener. Recruitment staff will help ensure eligible HCP participants are recruited for the study and send reminder emails to reduce no-shows.

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)
Number to complete the screener	140	.08 (5 min.)	11
Number to complete rescreening	70	.08 (5 min.)	6
Number to complete the study (included in number to complete screener and rescreening)	70	1.00 (60 min.)	70
Total			87

REQUESTED APPROVAL DATE: October 31, 2019

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