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

TITLE OF INFORMATION COLLECTION: Clinical Trial Data in Professional Prescription Drug Promotion

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

Several studies show that physicians are influenced by the way clinical trial results are reported. This may be a function of physicians' knowledge about clinical trial design, or their experience with and skill in interpreting statistics. Surveys find that physicians believe knowledge of biostatistics is important but have less knowledge than is needed to understand all clinical trial results. However, little is known about physicians' reactions to and understanding of clinical trial data presented in professional prescription drug promotion. We plan to conduct one-hour individual in-depth interviews via telephone that will provide FDA with information about physicians' reactions to and understanding of clinical trial data presented in professional prescription drug promotion. Qualitative methods will be used to assess physicians' (1) training in biostatistics and clinical trial design, (2) understanding of clinical trial design in general, and (3) understanding of clinical trial data as presented in prescription drug promotional materials. In addition, findings of this study will help to elucidate the impact of information presented in study stimuli (e.g., journal ads and other print promotional pieces directed at health care professionals) and explore whether there are differences between primary care physicians (PCPs) and specialists' responses.

2. **Intended use of information:**

OPDP has an active research program with funds committed for important projects. In order to maximize resources and anticipate future needs, it is necessary for OPDP to continuously explore avenues for future research. Qualitative research is a valuable tool for developing a future research agenda. The proposed interviews will allow us to investigate healthcare professionals' interpretation of clinical trial data included in professional advertising. This information collection will inform development of future quantitative research studies.

3. **Description of respondents:**

The study will consist of seventy-two (72) individual in-depth interviews with practicing physicians across the United States via telephone. General inclusion/exclusion requirements built into the screening protocol will ensure that all physicians are currently practicing and write at least fifty (50) prescriptions per week and have not participated in a research interview and/or focus group within the last three months.

Additional inclusion/exclusion participant requirements will be implemented via soft recruiting quotas. These soft quotas, as detailed below, will help to screen participants and to facilitate recruitment of a diverse group of participants reflective of the population of practicing physicians.

Two different types of physicians will be interviewed for this study. Two-thirds (48) of the physicians will be PCPs. The other physicians (24) will be specialists, specifically endocrinologists. The gender, race/ethnicity, and ages of the participating physicians will be self-identified by participants during the screening process. The goal is for the participating physicians to be generally reflective of the demographic composition of physicians in the U.S. according to the American Medical Association (AMA).

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

We plan to conduct the interviews between March 1, 2016 and June 1, 2016.

Physicians will be recruited to participate in this study from across the continental United States. At least one interview will be with a physician from the Washington, DC area. At least one interview will be with a physician from a small city (population less than 150,000) that is not in an otherwise major metropolitan area and that is not on the East Coast. Specialists will be from at least two cities. To provide coverage across a variety of large urban (e.g., Washington, DC), small urban (e.g., St. Louis, MO), and suburban/rural locations (e.g., Cortez, CO), the remaining participants will be selected according to urbanicity as determined by the Rural-Urban Continuum (RUC) code associated with the zip code at their place of employment.

5. **How the Information is being collected:**

Recruitment Procedures

FDA's contractor, Fors Marsh Group, will conduct recruitment procedures in collaboration with Doctor Directory. Doctor Directory is a search engine that the public can use to find physicians and that healthcare providers can use to list their practices. In the process of listing, healthcare providers have the option of opting in to market research studies through their proprietary panel. Recruitment procedures, conducted by Doctor Directory, will involve: (1) identifying and contacting potential participants, (2) screening potential participants, (3) scheduling participants, and (4) confirmation of participants.

Doctor Directory has a proprietary database of more than 800,000 practicing physicians, including specialists, whom have opted in to participate in research studies. Doctor Directory will identify potential participants and contact them for screening. Contact will be made via emails that include the study name, incentive information, time commitment required, and a link to the screening questionnaire (see attached recruitment emails).

Potential participants who are interested in taking part in this study will be directed to complete the online screening questionnaire (see attached). Approximately 300 physicians will be screened to obtain a final sample size of 72.

Method

The consent form (see attached) will be available online, programmed into the final part of the screener. After screening, eligible participants (i.e., the physicians who did not screen out) will be directed to read the consent form and if they decide to participate, electronically

provide consent and submit the form. Participants will then be directed to Doctor Directory's online scheduling tool to schedule a date and time for the interview.

We will use screen-sharing software (e.g., Zoom, GoToMeeting) in concert with telephones to conduct these remote interviews. Participants will be provided a dial-in number and link to access the screen-sharing software. Participants and the moderator will converse via telephone. Moderators will use the interview discussion guide to guide the interview (see attached). For part of the interview, moderators will use an online software platform to ask participating physicians to read and discuss their understanding of clinical trial data as presented in stimuli material. The stimuli materials are promotional materials for two prescription drugs. Participants will only be using their computer to view stimuli; no webcam will be used and the software will not require participants to download and install the platform to their computer.

We will audio record all interview sessions as well as provide remote login of the sessions for FDA and other study staff to observe the interviews live, including both the telephone discussion and real-time view of the stimuli being presented online. A "false close" will be implemented during which observers will have an opportunity before the close of each interview to ask individual participants additional questions based on his/her discussion. These interviews are anticipated to last one hour.

Participants will receive an incentive as a token of appreciation for participating in the interviews. For this study, PCPs will receive an honorarium of $150 and endocrinologists will receive an honorarium of $175 for the completion of the 60-minute interview. Fors Marsh Group will provide notification of completed interviews to Doctor Directory, which will then pay participants via company check, per standard procedures.

6. **Confidentiality of Respondents:**

All data will be collected with an assurance that the respondents' responses will remain private to the extent allowable by law. Both the consent form and the moderator's guide will contain a statement emphasizing that no one will be able to link a participant's identity to his/her responses and that each participant will only be identified by a unique ID. Researchers will not tie respondents' personal information to their answers. Additionally, moderators will not ask participants to provide identifying information as part of their responses (e.g., location of practice, name of practice, etc.); however, in order to establish a rapport with the participant, moderators will address participants by their first name. All analyses will be done in the aggregate and respondent information will not be appended to the data file used. Further, no identifying information will be included in the data files delivered to FDA.

Sessions will be audio recorded and livestreamed for reporting purposes. Only FDA personnel and other study team members directly involved in the research will view the livestream. Livestreaming connections will be secure, using industry standard firewalls and security practices. All data will be encrypted in transit using secure hypertext transfer protocol (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 utilized to create transcriptions of the interview sessions for reporting purposes. The consent forms will contain language that notifies participants of both the audio recording and livestreaming. Before each interview begins, the moderator will confirm consent by receiving verbal affirmation from the participants to audio record and livestream the session. Due the importance of complete data, in the event verbal consent for the audio recording is not given, the interview will not proceed.

After data collection is completed, copies of the audio recordings will be delivered to FDA along with transcripts of the audio-recorded interviews. These transcripts will be provided to FDA to provide a written record of the sessions. To ensure participant privacy, all personal identifying information (PII) will be redacted from the recordings and transcripts prior to delivery to FDA.

The following procedures will be used to ensure participant confidentiality before, during, and after fielding. (1) Full names of the participants will be used only for scheduling purposes and will not be used on any interview materials provided to FDA (e.g., typed lists of participants); instead, each participant will be assigned a unique ID by which they will be referred. Moderators will only address the participants by their first name (e.g., Mary). (2) Transferring of screening- and scheduling-related information between Doctor Directory and Fors Marsh Group will be conducted via a password-protected, secure FTP site. All screening-related information will not be tied to any PII, but identified and matched by the assigned unique ID. For scheduling information, this will be limited to first name, last name, email, and phone number(s). (3) Transcripts, audio recordings, and reports will not contain any PII. (4) Respondents will not be tied to their individual responses, and all analyses will be conducted on the aggregate (e.g., any quotes used reporting will not be attributed to specific participants).

Contractors will not share personal information regarding participants with any third party without the participant’s 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 form. Further, if a participant makes a direct threat of harm to his/herself or others, Fors Marsh Group reserves the right to take action out of concern for him or her and for others.

All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products). All identifying information, including information collected during screening and audio recordings, will be kept on a separate password-protected computer and/or in locked cabinets for a period of 3 years only accessible by the Fors Marsh Group, 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.

7. Amount and justification for any proposed incentive:

Participants will receive an incentive as a token of appreciation for participating in the interviews. Fors Marsh Group will provide notification of completed interviews to Doctor Directory, which will then pay participants via company check, per standard procedures.

As participants often have competing demands for their time, incentives are used to encourage participation in research. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation.[1] The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular research, we are asking physicians to provide thought-intensive, open-ended feedback on concepts that require a high level of engagement.

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[2] as well as provide enough motivation for them to participate in the study rather than another activity. Particularly in the case of primary care physicians and specialists, incentives need to be high enough to entice these physicians to make time in their busy schedules and participate in the study.

If the incentive is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with moderator and observer time.[3] Additionally, low participation can cause a difficult and lengthy recruitment process that in turn, can cause delays in launching the research, both of which lead to increased costs.

For this study, PCPs will receive an honorarium of $150 and endocrinologists will receive an honorarium of $175 for the completion of the 60-minute interview. Although market incentive rates for physicians are approximately $250 to $350 for similar research activities, with higher rates for specialists, we hope the flexibility the remote interview methodology affords—e.g., no travel time to/from facility, conducted on the physicians' schedules—will offset the lower honorarium.

8. Questions of a Sensitive Nature:

None.

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

No statistical methods will be used.

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

Table 1 shows the estimated annual reporting burden.

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1 Halpen, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(*7*), 801-803.

2 Russell, M.L., Moralejo, D.G., & Burgess, E.D. (2000). Participants' perspectives. *Journal of Medical Ethics*, *26*(*2*), 126-130.

3 Morgan, D.L. & Scannell, A.U. (1998). *Planning focus groups*. Thousand Oaks, CA: Sage.

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)	Total Hours
Number to complete the screener	300	1	300	.08 (5 min.)	24
Number to complete the study	72	1	72	1.00 (60 min.)	72
Total			372		96

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