FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF DATA TO SUPPORT DRUG PRODUCT COMMUNICATIONS (0910-0695)

TITLE OF INFORMATION COLLECTION: Remote Focus Groups: Prescription Drug Use Related Software (PDURS) Study

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   In light of recent technologies, a number of currently marketed prescription drug products incorporate microchip or Bluetooth technology to track administration of medication. Following are two examples: (1) Abilify Mycite uses a microchip in a product indicated for schizophrenia to connect to an app that records when patients take their medication; and (2) a new combination product involving Enbrel uses Bluetooth technology in the administration device to connect to an app to track medication usage.

   In many cases, no evidence exists that these products increase adherence; however, physicians and patients may infer some kind of adherence benefit from the technology. It is possible that providing additional information about the state of knowledge about adherence will influence these perceptions. We will explore these questions in a series of remote focus groups with physicians and consumers and address questions about how individuals will interpret limitation of use disclosures. For example, do people distinguish between a lack of data (i.e., "has not been shown to," or "it is not known") and unsupportive data (i.e., "has been shown not to")?[1] We will use focus groups as a first step toward a future quantitative study in an effort to obtain richer responses from individuals in their own language.

2. **Intended use of information:**

   We will use the results of this research to: (1) better understand what physicians and consumers know about and how they perceive PDURS; (2) examine how physicians and consumers interpret various disclosures related to limited available data about PDURS; and (3) inform future quantitative phases of this research project.

3. **Description of respondents:**

   We will select 18 primary care physicians (PCPs) out of a pool of 100. We will also select 18 consumers out of a pool of 50. This will give us a total of 36 PCPs and consumers.

   Inclusion criteria for PCPs include: (1) engaging in patient care at least half time, (2) treating patients with diabetes, (3) access to a computer with a webcam, audio, and high-speed Internet, and (4) willingness to have the focus group recorded by audio and video.

1For example, actual labeling language: "It is not known if ABILIFY MYCITE can improve how well you take your aripiprazole (patient compliance) or for changing your dose of aripiprazole."

Exclusion criteria for PCPs include: (1) participated in a focus group or other interview-based research in past 3 months, and (2) works in the marketing, advertising, or pharmaceutical industry or for the Department of Health and Human Services. We will strive to include a mix of ages, genders, and races and ethnicities.

Inclusion criteria for consumers include: (1) aged 18 years or older, (2) fluent in English, (3) diagnosed by a physician with diabetes, (4) currently receiving treatment (insulin or medication) for diabetes, (5) access to a computer with a webcam, audio, and high-speed Internet, and (6) willingness to have focus group discussions recorded by audio and video.

Exclusion criteria for consumers include: (1) participated in a focus group or other interview-based research in past 3 months, and (2) works full-time in the marketing, advertising, or pharmaceutical industry or for the Department of Health and Human Services. Like the PCP group, we will strive to obtain a mix of ages, genders, and races and ethnicities.

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

We plan to conduct focus groups between January 2022 and March 2022.

5. How the information is being collected:

Recruitment Procedures

PCPs. Staff from a focus group recruitment firm (Plaza) will use their in-house databases to recruit participants using an online screener (Appendix A). Eligible PCPs completing the groups will be offered $250 as a token of appreciation. Once a PCP agrees to participate in the focus group, a confirmation email letter (Appendix B) will be sent to them outlining the overall purpose of the research, specifying the date and time for the focus group and a Zoom.gov link for participating in the groups at the appointed time. An informed consent document (see Appendix C) will also be attached to the confirmation email letter.

Plaza will send recruited PCPs' first names to Westat as they are recruited. Westat will provide to FDA periodic updates about recruited PCP participants. Two days before the scheduled focus group, recruited PCPs will be sent a reminder email and offered an opportunity to decline participation, if they choose (Appendix B).

Consumers. Plaza will recruit consumers for the focus groups using a similar process as the PCPs. They will use their in-house database and an online screener (Appendix A) to recruit consumer participants. Eligible consumers completing the groups will be offered $75 as a token of appreciation. Once a participant agrees to participate in the focus group, a confirmation email letter (Appendix B) will be sent to the participant outlining the overall purpose of the research, confirming the date and time for the focus groups, and a Zoom.gov link for participating in the groups at the appointed time. An informed consent document (see Appendix C) will also be attached to the confirmation email letter. Plaza will send recruited participants' first names to Westat, which will be provided to

FDA. Two days before the scheduled focus group, recruited participants will be sent a reminder email and offered an opportunity to decline participation, if they choose. (Appendix B).

Data Collection Procedures

Data collection will be conducted remotely using Zoom.gov. Trained moderators from Westat will conduct the virtual focus groups. Before starting interviews, the moderator will review the informed consent document sent to participants (sent in advance with the confirmation email letter) and request their verbal consent to participate in the study and record the discussion.

Using a semi-structured guide (Appendix D), the moderator will ask participants to describe their familiarity with PDURS and their reactions to various PDURS descriptions. No sensitive questions will be asked of participants. The expected length of each focus group is 60 minutes.

Westat will audio record all focus group sessions as well as provide remote login 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 moderator will be able to interact with participants.

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 participants will receive an informed consent document (Appendix C) 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 telephone 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.

At the beginning of the interview, the moderator will review the key elements of the informed consent document (e.g., study purpose, participant rights, potential risks and benefits, presence of observers) with participants. Participants will then be asked to provide their verbal consent to participate in the study and record the discussion. Participants that do not give their consent for the audio recording will not be able to participate in the focus group.

All data will be collected with an assurance that responses is kept secure to the extent permitted by law. The informed consent document and the moderator's guide contain a statement emphasizing that no one will be able to link a participant's identity to the

participant's responses. Moderators 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. Furthermore, no identifying information will be included in the data files that Westat delivers to FDA.

All focus groups will be audio recorded for reporting purposes and will be livestreamed for observers. The livestreamed and recorded focus groups will only be viewed by FDA and Westat project staff. Livestreaming connections will be secure and use industry-standard firewalls and security practices. All data will be encrypted in transit using hypertext transfer protocol secure (HTTPS). All equipment will be operated and maintained according to industry-standard practices, and all software will be validated using industry-standard quality assurance practices. Audio recordings will be used to create transcriptions of the focus group sessions for reporting purposes and destroyed within 3 years after project completion.

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

Recordkeeping and Confidentiality

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

(1) Plaza will recruit and schedule participants from their in-house databases. Only first names of scheduled focus group participants will be provided to Westat. Any focus group materials Westat shares with FDA will only contain participants' first names and whether they are a PCP or a consumer.

(2) During the focus group discussion, 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 for a period of no longer than 3 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 consistent 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:

PCPs. Historically, physicians have been 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., Keating et al. 2008; Dykema et al. 2011; Ziegenfuss et al. 2012) have discussed the challenges of conducting research with healthcare providers 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 (Asch et al. 2000). 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 (Epley and Gilovich 2006; Höhne and Krebs 2017; Saris et al. 2010; Krosnick and Presser 2009). 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 (VanGeest et al. 2007). 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 (Martins et al. 2012). 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., Converse and Presser 1986; DeVellis 2016) and by ensuring participation from a cross section of physicians, which will help data quality by improving validity, and reliability.

In the proposed study, we will offer incentives in the amount of $250 for PCPs for 1 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, the flexibility of our interview methodology—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 study, we are asking PCPs 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 the following:

(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 physicians—for example, early morning, evenings, lunch.

(3) Having the flexibility and appropriate staff available to run concurrent sessions to leverage popular session times.

Consumers. To prepare for these focus groups, we consulted with focus groups recruitment vendors to determine an acceptable incentive rate. Based on these consultations, we propose an incentive of $75 as a token of our appreciation to participants. All focus group participants will receive their incentives after groups have been completed. This ensures that we can attract participants who meet our screening requirements to participate in the online focus groups and improve the likelihood that they will log on and participate in the discussion.

The proposed incentive amount is considered below-market rate for focus groups. Vendors estimate that studies conducted with similar populations and level of effort in this market in 2020 to 2021 provide incentives of $100 to $150. Our proposed incentive is based on approximately 70 minutes of their time on this effort, which includes logging in early to confirm technical operations (10 minutes) and time to participate in the focus group discussion (60 minutes). We also note that 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.

Based on prior experience, 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. Low or nonmonetary incentives generally produce participation rates no better than the complete absence of any incentives (Church 1993; Dykema et al. 2012; Singer and Kulka 2002). The consequences of offering 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 places additional burden on the recruited participants who must reschedule their participation in the focus group.

8. Questions of a Sensitive Nature:

None.

9. Description of Statistical Methods (i.e. Sample Size and 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. Participants will be recruited from a focus group recruitment vendor using their in-house database and a screener. Recruitment staff will help ensure that eligible 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)
Screening (Physicians)	100	5/60	8
Focus Groups (Physicians)	18	70	21
Screening (Consumers)	50	5/60	4
Focus Groups (Consumers)	18	70	21
Totals			54

*Participation time for the focus groups includes 10 minutes for participants to log on and test the online platform and 60 minutes for participation in the focus group discussion.

REQUESTED APPROVAL DATE: January 31, 2022

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