FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "FOCUS GROUPS ABOUT DRUG PRODUCTS" (0910-0677)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Focus Groups on Oncology Indications

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   Oncology products are increasingly being promoted to consumers via direct-to-consumer (DTC) television advertising. Oncology indications are often complicated, with different endpoints such as overall survival, overall response rate, and progression-free survival. These focus groups are the first step in a research project that will help determine how to communicate oncology indications and endpoints in DTC television ads.

2. **Intended use of information:**

   These focus groups will provide FDA with information about how consumers understand oncology indications and endpoints. We will also use the qualitative data gathered here to create stimuli for a future quantitative study of oncology DTC television advertising. The long-term objective is to ensure effective communication of prescription drug information.

3. **Description of respondents:**

   To be eligible to participate, respondents have to be able to read, understand, and speak English. Individuals will be ineligible for participation if they have other characteristics that could potentially bias responses (e.g., employment in the healthcare, pharmaceutical, or marketing industry or with the Department of Health and Human Services) or if they have participated in market research in the past 3 months. For the "consumers previously diagnosed with cancer" group, participants will be eligible if they have been diagnosed with a solid tumor or hematologic cancer and are no longer receiving treatment for their cancer. Participants diagnosed with skin cancer, other than Kaposi's sarcoma or melanoma, will be excluded. Finally, to be eligible participants will need to indicate that they are at least somewhat comfortable asking their physician to explain something that they are confused about. This item is related to the power distance between the patient and their physician.[1] Participants with a larger power distance may be more likely to

1 Gao, G., Burke, N., Somkin, C. P., & Pasick, R. (2009). Considering culture in physician—patient communication during colorectal cancer screening. *Qualitative Health Research*, *19*(6), 778–789.

defer to their physician for medical decisions, which could make their responses to the focus group questions less helpful than participants who are not as dependent on their physicians for medical advice.

We will recruit participants who are diverse in terms of age, sex, race, and other demographics and will exclude related individuals (e.g., siblings, spouses). The cancer diagnosis groups will include an even mix of participants previously diagnosed with either solid tumor or hematologic cancers.

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

We anticipate the focus groups will take place in April and/or May 2019, or within six weeks following RIHSC and OMB approval. The following cities were selected to represent the Midwest, East, South, and West regions: Minneapolis, MN; Philadelphia, PA; Raleigh, NC; and Walnut Creek, CA. If we are unable to conduct focus groups in one of the four cities, we will identify an alternate city within the same region.

5. How the Information is being collected:

Recruitment Procedures

FDA's contractor, Research Triangle International (RTI), will work with local market research firms in each of the cities to recruit participants and provide the facilities for hosting the focus group discussions.

The market research firms will identify potential participants in their respective cities through existing contact databases and media advertisements. The firms will contact potential participants by telephone or email and screen them for eligibility using a screener approved by the FDA (attached). If interested and eligible, individuals will be scheduled for focus groups on preselected days in each city.

After each person agrees to participate, the market research firms will send them a confirmation email that lists the date, time, and location of their focus group session. The firm will also call participants the day before the focus group session to remind them of the session and confirm that they plan to attend.

The firms will overrecruit four individuals for each group to ensure sufficient participation in case of no-shows or last-minute cancellations. RTI will work with the market research firms to closely monitor the progress of recruiting. The firms will provide frequent updates throughout the recruitment process, providing RTI with data from the screener on these eligible participants and basic demographic information. Before each focus group, the market research firms will provide RTI and FDA with participants' screening responses, which RTI will review to confirm eligibility.

Method

Eight focus groups (two in each of the four locations across the United States) will be conducted. When participants arrive at the facility, they will be provided with an informed consent form (attached). The focus group moderator will use a discussion guide and associated materials (attached) to guide and conduct the focus group sessions. The

focus groups will all explore participants' understanding of common oncology clinical trial endpoints (e.g., overall survival). Half of the groups will focus on this exclusively, while half will also discuss advertising claims and disclosure related to these endpoints.

Focus group sessions will be audio recorded, and remote login information will be provided to study staff to observe the focus groups in real time.

Focus groups will last approximately 60 minutes.

6. Number of focus groups:

We plan to conduct eight focus groups; four with participants from the general population and four with participants with a cancer diagnosis.

7. Amount and justification for any proposed incentive:

Participants will receive a $75 incentive for participating in the focus groups. Following OMB's "Guidance on Agency and Statistical Information Collections," we offer the following justification for our use of this incentive.

Burden on the respondent: This data collection involves in-person focus groups. 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.[2] The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort that they expend to participate. Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[3] as well as to provide enough motivation for them to participate in the study rather than another activity.

Data quality/Improved coverage of specialized respondents, rare groups, or minority populations: This data collection involves recruiting participants with a cancer diagnosis. Previous research suggests that providing incentives may help reduce sampling bias by increasing rates among individuals who are typically less likely to participate in research.[4] Furthermore, there is some evidence that using incentives can reduce nonresponse bias in some situations by bringing in a more representative set of respondents.[5]

Reduced survey costs: 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.[6] Additionally, low participation can cause a difficult

2 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.

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

4 Guyll, M.., Spoth, R.., & Redmond, C. (2003). The Effects of Incentives and Research Requirements on Participation Rates for a Community-Based Preventive Intervention Research Study. *Journal of Primary Prevention*, vol. *24*(1), pp. 25-41.

5 Castiglioni, L., & Pforr, K. (2007). The effect of Incentives in Reducing Non-Response Bias in a Multi-Actor Survey." Presented at *The 2nd Annual European Survey Research Association Conference*, Prague, Czech Republic; Singer, E., (2006). Nonresponse Bias in Household Surveys. *Public Opinion Quarterly*, vol. 70(5), pp. 637-645.

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

and lengthy recruitment process that in turn, can cause delays in launching the research, both of which lead to increased costs.

8. Questions of a Sensitive Nature:

Upon arrival at the market research facility, participants will read and sign an informed consent form. The consent form describes the purpose of the study, how the information will be collected, benefits and risks to participation, plans for observation (in real time and through audio and video recordings), potential risks and benefits, the right to refuse or withdraw and the voluntary nature of participation, and payment for participation. The consent form also describes how some questions may be considered sensitive in nature and that the discussion will revolve around the context of serious illness, given that we will be discussing cancer treatment outcomes. This topic may be distressing to participants who have experienced serious illness themselves or who have had a close family member experience a serious illness. The discussion guide is not designed to encourage personal recounts of serious illness, and the moderator will be trained to deal with these recounts sensitively if they occur. Participants will also be reminded that their participation is voluntary, that they may take a break at any time, withdraw from the study, and that they do not have to answer any questions they do not wish to answer. Contact information for the RTI project director and the RTI Office of Research Protection will also be provided. Finally, the form describes the procedures in place to protect confidentiality: nondisclosure of personally identifiable information (PII), the inability to link individual responses to PII, reporting in aggregate such that individuals cannot be identified by name, storage of study documents and information, and eventual destruction of study files, including audio and video recordings.

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):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Number to complete the screener	347 for cancer diagnosis; 104 for general population	5	40
Number to complete the study	72	60	72
Total	451		112

To create estimates of the number of respondents to be screened, we assumed a 15% eligibility rate for participants with a cancer diagnosis, a 50% eligibility rate for general population participants. These estimates also assume we will need to invite 13

respondents for each group for 9 to ultimately participate (i.e., over-recruitment to account for no-shows).

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