U.S. Food & Drug Administration

Data To Support Social and Behavioral Research
as Used by FDA

OMB Control No. 0910-NEW

SUPPORTING STATEMENT—Part B: Statistical Methods

1. Respondent Universe

Study participants will include members of the general public and stakeholders with an interest in or experience with drug products. These may include patients who take medications, pharmacists, physicians, or other health care providers. Inclusion and exclusion criteria will vary depending on the research topic. To identify potential variation according to regional differences, information collections may be conducted at multiple sites in the United States when appropriate.

The study samples will be selected from an appropriate demographic, including members of online community groups, or samples obtained through in-person intercepts or mailings (e.g., in health care facilities, community centers). Sampled respondents will be invited to participate in the information collection through a various number of methods, such as: email, letters, in and in-person interviews. Respondents who choose to participate will complete a screener questionnaire and, if eligible, participate in the study. Studies will be monitored to ensure samples are diversely representative in terms of age, gender, education, and ethnicity/race. Other sources of samples may also be employed. Recommended methodologies and sample sizes will be based on a review of the relevant literature, consultation with experts in the field, and previous studies, regardless of source.

In qualitative studies, quota sampling is often used to select a convenience sample of individuals who meet certain criteria that reflect characteristics typical of the demographic. Response rate is not applicable to quota sampling because this type of sampling results in a nonprobability sample not representative of the population. In qualitative studies, respondents are initially contacted by telephone or by mail; where over-recruiting is done to compensate for non-responsive follow-ups.

Where quantitative methods are used, information collection activities will target the particular demographic with statistical sampling procedures employed to identify potential respondents. Mail, telephone, and internet surveys typically will seek a sample that has a reasonable diversity in key demographic characteristics such as age, gender, education, and race/ethnicity.

2. Procedures for Information Collection

Qualitative data collection will consist of interview, small group, and focus group methodologies, i.e., qualitative methods. In qualitative studies, an individual or small group of people engage in a discussion on selected topics of interest typically directed by a moderator/interviewer who guides the discussion in order to obtain the person or group's opinions, perceptions, behaviors, or attitudes. Interviews and focus groups capture the insights of an individual, or the collective insight of a group while preserving individual preferences. In groups, participants can describe their experiences and preferences without the limitations of preset response categories determined by investigators. Furthermore, interviews and focus groups produce rich data complete with nuances that often may be obscured in quantitative data collection techniques. The methods are used to produce qualitative data to help develop and design educational interventions or communications, and interpret quantitative results obtained from surveys or experiments.

Since interviews and focus groups are qualitative research methodologies, statistical methods will not be employed to analyze interview or focus group data, as it is not appropriate to report the percentage of focus group participants who expressed a particular view. Typically, not every participant in a group comments on every issue discussed, and the course of discussion will vary across groups, with some topics emerging in one group and not in another. Instead, descriptors such as "*many*," "*several*," and "*few*" may be used to qualitatively describe the relative number of participants or groups who expressed a particular view.

For most quantitative studies submitted under this generic clearance, FDA will use surveys, either through internet-based surveys, phone surveys, in-person surveys, or mailed surveys. When participants are recruited for survey participation the vendor will send invitations to the target audiences. Each invitation will contain the title, an explanation of the research being conducted, the expected length of the participation, any incentive amount that may be provided for successful completion of the survey, and how an individual's data will be kept confidential.

3. Methods to Maximize Response Rates

Participants will be recruited from sources offering the greatest likelihood of reaching the target demographic. In the past, participants have been recruited from commercial databases or through convenience sampling procedures. To minimize the possibility of having too few appropriate participants (thereby forcing group cancellation) or too few interview/survey participants, more participants may be invited than will be used. In the event that too many participants report, excess participants will be dismissed. For quantitative methods, FDA will implement several procedures to increase participation wherever possible. We will conduct cognitive interviews and pretests to help improve understandability of the questionnaire, to reduce participant burden, and to enhance administration. We will keep the questionnaire at a reasonable length to minimize break-offs. Tested recruitment and data collection procedures will be used to maximize cooperation and to achieve the desired response rates.

4. Tests of Procedures or Methods to be Undertaken

Pretesting of interview and focus group protocols to be used in these qualitative studies may be done with internal staff or a limited number of external individuals. If the number of pretest respondents exceeds nine members of the public, the agency will submit the pretest focus group protocol for review under this generic clearance.

Before each information collection is implemented, a pilot test the collection/survey instrument(s) and method of data collection will be conducted when possible. Lessons from the pilot test will be identified, and changes, as necessary, will be incorporated accordingly. All pilot tests will involve no more than nine individuals unless OMB clearance is sought for more than nine.

FDA may conduct cognitive interviews to evaluate and refine a draft questionnaire or other study materials. If the number of cognitive interview respondents exceeds nine members of the public, the agency will submit the cognitive interview protocol for review. The cognitive interviews will help identify areas where the collection/survey instrument was ambiguous, burdensome, or confusing for respondents, and the survey or other study materials will be revised accordingly.

Additionally, FDA may conduct a pretest with individuals to thoroughly test the programmed questionnaire. At the conclusion of the pretest, all strategies, algorithms, and programs for sampling, survey administration, and data compilation will be tested, validated, and readied for launch of the data collection instrument. The collection instrument will be revised based on the pretest findings.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

FDA primary investigators, staff, and contractors will be responsible for developing study materials, including the moderator guides and screening criteria, with advice, if needed, from data collection contractors. Sometimes, contractors may compile top line findings in the final report if necessary.