

United States Food and Drug Administration

Data to Support Cross-Center Collaboration for Social Behavioral Sciences Associated with Disease Prevention, Treatment and the Safety, Efficacy, and Usage of FDA Regulated Products

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part B: Statistical Methods

1. Respondent Universe and Sampling Methods

Study participants will include members of the general public and other stakeholders with an interest in or experience associated with the disease, disease prevention, treatment, and the safety, efficacy, and usage of products overseen by the agency. These may include patients, consumers, caregivers, or academic/scientific experts who have experience associated with the disease, disease prevention, treatment, and/or use FDA-regulated products, as well as pharmacists, physicians, veterinarians, medical provider, or other public health professionals. Inclusion and exclusion criteria will vary depending on the research topic. To identify potential variation due to regional differences, information collections may be conducted at multiple sites in the United States when appropriate.

FDA will select the study participants, referred to as the study samples, from the target population. FDA will use various methods, such as emails, market research panels, and mailings, to invite potential respondents to participate in the information collection. Respondents will complete a screener questionnaire and, if eligible, participate in the study. FDA will monitor the study to ensure samples are representative of the target demographic in terms of age, gender, education, sexual orientation and race/ethnicity, and other demographic categories as deemed appropriate, with a targeted survey response rate of 75 percent.. The agency may also use other sources of samples, for example, online community groups and in-person interviews conducted at various locations such as health care facilities, veterinary clinics, and community centers where the target demographic tends to be concentrated. 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 target demographic. Respondents are initially contacted by telephone or by mail and over-recruiting is done to compensate for non-responsive follow-ups.

In quantitative studies, statistical sampling procedures are often used to identify potential respondents within the target demographic. Mail, telephone, and internet surveys typically result in a sample that is reasonably diverse in key demographic characteristics such as age, gender, education, and race/ethnicity.

2. Procedures for the Collection of Information

Qualitative data collection will consist of individual interviews, small group, and focus group methodologies. 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, small groups, and focus groups capture the insights of an individual, or the collective insight of a group while preserving individual preferences. 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. Such qualitative methods produce data that will help FDA develop and design, for example, better educational interventions or communications, and interpret quantitative results obtained from surveys or experimental studies.

Because interviews, small groups, and focus groups are qualitative methods, FDA will not use statistical methods to analyze the collected data, as it is not appropriate to report the percentage of focus group and interview 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 indicate 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, such as internet-based surveys, mobile technology-based surveys, telephone surveys, in-person surveys, or mailed surveys. When participants are recruited for survey participation the vendor will send invitations to members of the target audience. Each invitation will contain the title, an explanation of the research being conducted, the expected length of the participation, any payment or gift that may be provided upon successful completion of the survey, and how an individual's data will be kept confidential.

3. Methods to Maximize Response Rates and Deal with Non-Response

Participants will be recruited from sources that are most likely to reach 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. FDA will conduct cognitive interviews and pretests to help improve understandability of the questionnaire, to reduce participant burden, and to enhance administration. FDA 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

FDA may ask internal staff or a limited number of external individuals to conduct a pretest of the protocols to be used in qualitative studies. 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, FDA will conduct a pilot test of the collection/survey instrument(s) and method of data collection 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 individual in-depth interviews to evaluate and refine a draft questionnaire or other study materials. If the number of individual in-depth interview respondents exceeds nine members of the public, the agency will submit the protocol for OMB review. The individual in-depth interviews will help identify areas where the collection/survey instrument is 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 survey 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, cooperative agreement grantees and contractors will be responsible for developing study materials, including the moderator guides and screening criteria, with advice, if needed, from data collection contractors or cooperative agreement grantees. Sometimes, contractors or cooperative agreement grantees may compile top line findings in the final report if necessary.