United States Food and Drug Administration

Medical Conference Attendees' Observations about Prescription Drug Promotion

OMB Control No. 0910-NEW

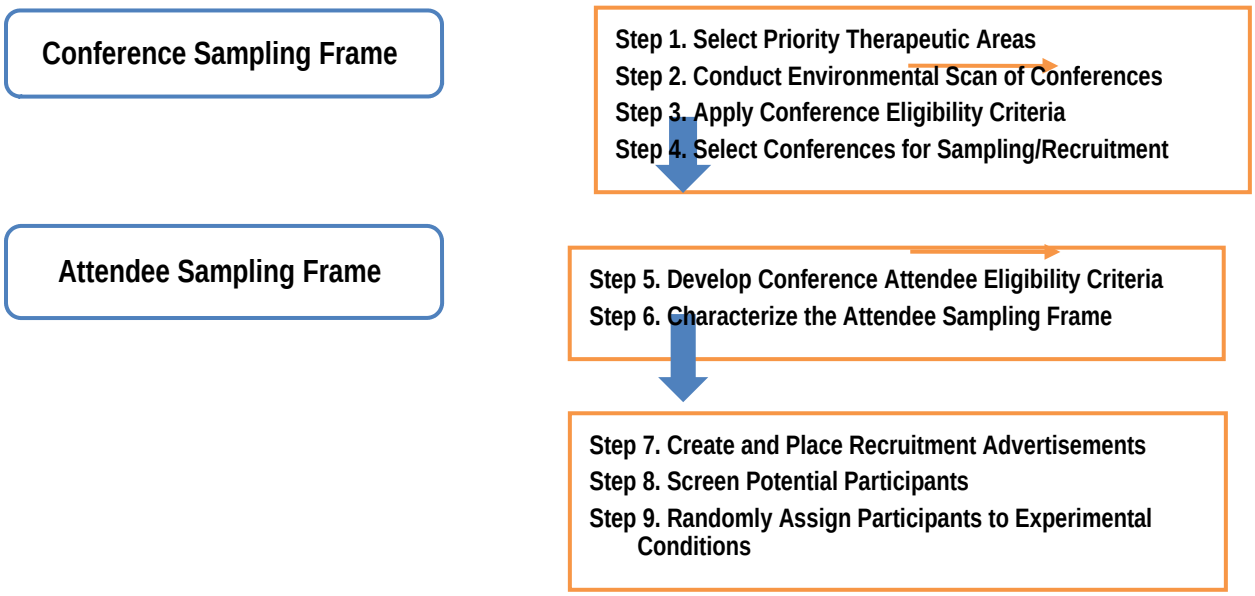
SUPPORTING STATEMENT

Part B. Statistical Methods

1. Respondent Universe and Sampling Methods

To complete this research, we will recruit attendees of large medical conferences in the United States over the course of one year. These conferences will represent a variety of specialties to reflect medical areas that have prescription treatments that may be promoted to healthcare providers (HCPs). Specifically, we will enroll HCPs who attended one of 12 selected medical conferences into an online survey within 7 days of conference attendance. Exhibit 1 summarizes our approach to: (1) determining the conference sampling frame; (2) determining the attendee sampling frame; and (3) recruiting and enrolling the target sample in the online survey.

Exhibit 1. Sampling Frame and Participant Recruitment Process



- high volume of prescriptions written

- large patient population
- high amount of new drug development and promotional spending

Exhibit 2 shows the final criteria for conference inclusion. Conferences that meet these criteria were selected based on an environmental scan.

Exhibit 2. Conference Eligibility Criteria

Criterion	Parameters
Therapeutic area	Associated with one of the prioritized therapeutic areas
Conference attendance	Estimated attendance of 5,000 or more individuals
Target audience	Focused on prescribers and clinicians (e.g., not insurers)
Event date	Scheduled during August 2021–August 2022
Event location	Domestic (within United States)

When data collection commences, medical conference attendees at each conference will be randomly selected, invited to participate, and screened to ensure they are HCPs with prescribing authority who responded to the survey invitation within 7 days of attending the target conference. HCPs will be limited to physicians, nurse practitioners, and physician assistants who spend 20% or more time in direct patient care, are able to read and speak English, are not currently employed by the federal government or a pharmaceutical company (not including occasional consulting), and have not participated in another wave of the project.

2. Procedures for the Collection of Information

Part A of the supporting statement described the rationale for conducting the study.

The online survey will be broken into two main parts—(1) a cross-sectional survey designed to capture HCP observations from the medical conference; and (2) an experimental study designed to assess how data disclosures and exhibit booth representative background influence HCP perceptions of promoted prescription drugs. The cross-sectional part of the survey will contain a series of close- and open-ended questions. The experimental study part of the survey will ask participants to view a brief video simulating a conference exhibit hall interaction between an HCP attendee and a booth employee and then answer questions about a fictitious prescription drug featured in the video. Exhibit 3 shows our proposed study design and sample size across 12 conferences.

Exhibit 3. Study Design and Target Sample Sizes

Disclosure	Booth Employee Background		Total
	Business	Medical	
Present	*n*=92	*n*=92	**184**
Absent	*n*=92	*n*=92	**184**

TOTAL	184	184	368

Research Questions

In the survey part of the study, we plan to address the issue of how firms communicate about prescription drugs from the perspective of medical conference/exhibit hall attendees. Specifically, we will ask for attendees' general observations of:

a. Disclosures or disclaimers accompanying exhibit hall presentations and/or symposia (about data limitations, contrary data, FDA approval status, financial/affiliation sponsorship, etc.);
b. Publications or references accompanying the presentation of information (PI for approved indications, contrary data references, etc.);
c. What type of studies are being reported (real world evidence, pharmacokinetic/pharmacodynamic studies, meta-analyses, etc.);
d. Who makes the presentations (field of study, training);
e. Where the presentations are made (poster session, scientific floor, exhibit hall).

Hypotheses

As described above, embedded in the survey is an experiment with random assignment to conditions. We will examine the presence or absence of a disclosure and the educational/professional background of the pharmaceutical representative.

Hypothesis I

Participants who see information about the limitations of data will report less positive perceptions of the promoted product than those who do not.

Hypothesis II

Participants who see the pharmaceutical representative with a medical background will have more positive perceptions of the promoted drug than those who see the pharmaceutical representative with a business background.

Hypothesis III

The difference in perceptions between conditions with and without a disclosure will be smaller in the medical background condition than the business background condition.

Power & Analyses

Given our analytical goals and sampling frame, we have planned for a total sample size of 368 completed participants (*n*=92 per experimental condition; approximately 30 per medical specialty). This will provide us with sufficient statistical power (0.80) to detect small- to medium-sized effects in our primary analysis using a p-value threshold of 0.05.

Our primary analyses will examine: (1) differences in continuous outcome variables (e.g., perceived risk, perceived credibility) by disclaimer status (present vs. absent); (2) differences in continuous outcome variables by booth employee credentials (MD vs. MBA); and (3) differences in continuous outcome variables driven by an interaction between disclaimer status and booth employee credentials.

For these analyses, we will conduct two-way between-subjects (i.e., independent sample) ANOVAs for each outcome variable followed by pairwise comparisons using independent sample t-tests. This will provide us with 0.80 power to detect small to medium effect sizes (f = 0.146 and d = 0.415).

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

The study will be administered via Internet. To help ensure that the participation rate is as high as possible, FDA and the contractor will:

- Design a protocol that minimizes burden (short in length, clearly written, optimized for completion on mobile devices, and with appealing graphics);

- Use incentive rates that meet industry standards. In addition to offsetting respondent burden, using market-rate incentives tends to increase response rates, reduce sampling bias, and reduce nonresponse bias.

Participants will be convenience samples, rather than probability-based samples of U.S. HCPs. Rather, the strength of the experimental design used in this study lies in its internal validity, on which meaningful estimates of differences across manipulated conditions can be produced and generalized. This is a counterpoint to observational survey methodologies where estimating population parameters is the primary focus of statistical analysis. The recruitment procedures in this study are not intended to fit the criteria for survey sampling, where each unit in the sampling frame has an equal probability of being selected to participate. In an observational survey study, response rates are often used as a proxy measure for survey quality, with lower response rates indicating poorer quality. Nonresponse bias analysis is also commonly used to determine the potential for

nonresponse sampling error in survey estimates. However, concerns about sampling error do not generally apply to experimental designs, where the parameters of interest are under the control of the researcher—rather than being pre-established characteristics of the participants—and each participant has an equal probability of being assigned to any of the experimental conditions.

Generally, there are several approaches to conducting a nonresponse bias analysis, such as comparing response rates by subgroups (e.g., medical specialty), comparing respondents and nonrespondents on frame variables (e.g., gender, race, years in practice), and conducting a nonresponse follow-up study. For the proposed project, we will examine nonresponse for its descriptive value by comparing our full sample with population estimates for age, race, gender, and years in practice.

4. Test of Procedures or Methods to be Undertaken

   Before finalizing the protocol, we conducted nine remote cognitive interviews with physicians to ensure question flow and wording.

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

   The contractor, RTI, will collect and analyze the data on behalf of FDA as a task order under Contract HHSF223201510002B. Douglas Rupert, M.P.H., 919-541-6495, is the Project Director for this project. Data analysis will be overseen by the Research Team, Office of Prescription Drug Promotion (OPDP), Office of Medical Policy, CDER, FDA, and coordinated by Amie C. O'Donoghue, Ph.D., 301-796-0574, and Kathryn J. Aikin, Ph.D., 301-796-0569.