

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

TITLE OF INFORMATION COLLECTION:

Collection of Data to Support “Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Physician Interviews on Experiences with REMS Programs”

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA) has limited data to determine the impact of Risk Evaluation and Mitigation Strategy (REMS) programs. REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS may include one or more of the following such as: (1) A Medication Guide or Patient Package Insert for patients; (2) a Communication Plan for healthcare providers; and (3) Elements to Assure Safe Use (ETASU), which often involve some form of restricted distribution or evidence of safe-use conditions.¹ REMS programs focus on preventing, monitoring, and/or managing a specific serious risk by informing, educating, and/or reinforcing actions to mitigate the frequency and/or severity of an adverse event.

FDA has contracted with Brigham and Women’s Hospital affiliated with Harvard Medical School to conduct the REMS Programs to Promote Appropriate Medication Use and Knowledge. They will conduct the study to better understand how REMS programs have operated in practice and to use this information to develop actionable steps for improvement. Specifically, this study seeks to answer: (1) to what degree the terms of REMS programs have been followed; (2) how REMS programs have impacted drug utilization, health outcomes, and physician and patient experiences; and (3) how effectively REMS programs translate important risk-benefit information to physicians and patients. One task to meet these study objectives entails physician interviews about experiences with select REMS programs. We have already submitted an information collection request for patient REMS program experiences pertaining to another aspect of the overall study which OMB has already cleared.

2. Intended use of information:

The contractor will analyze the data collected from participants to assess physician experiences enrolling in REMS programs and complying with REMS program requirements as well as physician knowledge of REMS program rationales and structures. By leveraging interdisciplinary expertise, the results of the findings will be used to better understand real-world experiences with the REMS programs. This information will be included with other analyses to recommend actionable steps to support and improve the REMS programs.

¹FDA website: [Risk Evaluation and Mitigation Strategies](#), Accessed on Oct. 25, 2021.

3. Description of respondents:

Eligible participants will constitute physicians who have prescribed one of three REMS program-covered drugs assessed as part of the study that are less widely used—alemtuzumab, alvimopan, and pegvaliase. Up to 60 participants will be recruited for each REMS program through outreach to professional societies. For each group, the contractor will ensure a reasonable degree of geographic and demographic diversity, including race and ethnicity, sex, and age.

4. Date(s) to be conducted:

The sponsor will conduct the physician interviews between 1/1/2022 and 12/31/2022 and conduct the full study between 1/1/2022 and 06/30/2023.

5. How the information is being collected:

Using an interview guide, the contractor will conduct qualitative phone interviews with each participant lasting up to one hour. Audio recordings of the patient interviews will be transcribed.

6. Confidentiality of respondents:

The contractor will record personal details of each participant (i.e., name and address) solely for the purpose of collecting initial screening information and providing payment. Once the testing is initiated, the contractor will use a numbering system to protect the identity of each participant and to remove the link between personal details and test data.

At no stage during the recruitment process will the recruiters seek to gain access to any medical records for any participant. The study team will keep personal details and will not circulate them to any third party.

All study personnel interacting with human subjects as part of this research will have completed training on the protection of human subjects.

The contractor will present each participant with a consent form explaining the purpose of the study, what participation entails, the availability of a small gift card as a token of appreciation, the right not to participate, and contact information for the principal investigator and IRB. Consent will be presumed based on participation (see Consent Form).

7. Amount and justification for any proposed incentive:

As a token of appreciation, the contractor will offer a \$100 Amazon gift card to physician participants. All physician interviewees will receive this token from the contractor electronically after completing an interview. This is below the Federal recommendation of a token between \$150 and \$175 for a 60-minute interview. Studies have shown that health care providers are more difficult to recruit as study population compared to members of the general population due to demanding and often unpredictable schedules.

A study that randomly assigned physicians to four compensation groups for a survey—no incentive, \$200 lottery, \$50 incentive, and \$100 incentive—found that response rates were highest in the \$100 incentive group at 25.4% (Dykema et al., 2011). Furthermore, they found a meaningful difference in the response rates of the \$100 and \$50 incentive groups (25.4% v. 15.4%). Past OMB-approved studies have used monetary incentives of varying amounts as a token of appreciation to physicians who complete surveys. For example, in the study “FDA Survey of Physicians’ Perceptions of the Impact of Early Risk Communication about Medical Products” (OMB control number 0910-0615), the standard token was \$75 for a telephone survey that included both primary care physicians and specialists. In another study “Survey of Health Care Practitioners for Device Labeling Format and Content,” (OMB control number 0910-0790), the token of appreciation for physicians was \$200.

To motivate participation in the interview, the contractor will offer a \$100 Amazon gift card to physician interviewees as a token of appreciation. The amount of the token of appreciation reflects industry best practices and resembles tokens of appreciation for similar type of studies the contractor conducted in past years. Historically, physicians have been one of the most difficult populations to survey, primarily due to busy and often uncertain schedules. Setting appropriate monetary incentives in studies involving physicians is key to ensure a sufficient sample size and minimize the risk of selection bias.

Because the interviews in this project will be distributed to specialist physicians, the contractor would like to offer a \$100 token of appreciation. Furthermore, the cohort of drugs these interviews focuses on are prescribed by a smaller number of physicians due to their indications and the REMS certification process required. As a result, the contractor is already planning intensive recruiting cycles to ensure that they obtain the number of interviewees needed. This is better aided by a slightly higher monetary incentive. The contractor also would like to standardize physician payments across the multiple components of this project, one of which calls for physician experience surveys. The contractor is offering a \$100 incentive for the surveys, and the token of appreciation for the interviews is consistent with this amount.

8. Questions of a sensitive nature:

We do not expect any questions that would be sensitive in nature. Participants will be allowed to abstain from answering if they are uncomfortable with any questions. Additionally, participants will be notified at the beginning of the study session that they are welcome to end the session at any time for any reason.

9. Description of statistical methods:

The contractor will strip transcribed interviews of personal identifiers and import them into qualitative analysis software package. After reading each transcript independently, the contractor will draw up a list of exploratory codes that best captures the ideas in the interviews and conduct an initial round of coding. The contractor will then review the text for each code and determine whether changes to the code list are needed. Using a final code list, the contractor will recode the transcripts and examine the interrelationship

between: (1) the codes, (2) the range and gravity of themes particular to each stakeholder, (3) the diversity of responses within themes, and (4) the nature of responses to specific REMS components.

BURDEN HOUR COMPUTATION:

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Interview Respondents	60	60	60

REQUESTED APPROVAL DATE: December 2021

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