

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

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:

Evaluating a Structured Reporting Template to Increase Transparency and Reduce Review Time for Healthcare Database Studies

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of Need:

Real world evidence from real world data (RWD) increasingly informs high stakes decision making in healthcare. However, generating high quality evidence from secondary data that is not collected for research purposes can involve numerous complex design and analytic decisions. Because of this, reviewing evidence from studies conducted with RWD, such as administrative or clinical healthcare databases, can require substantial staff time within regulatory and other organizations.

Transparent reporting on key design and technical implementation parameters would streamline and increase efficiency for stakeholders who need to report or review such evidence. The aim of this project is to gather feedback from a wide range of stakeholders about a structured reporting template that presents key study parameters clearly and concisely in tabular and visual formats. Stakeholders' input will be used to provide feedback about the structured reporting template to better meet the needs of various stakeholder groups involved in generating or evaluating evidence from database studies. Stakeholders who do not agree to participate will not be a part of the study. We have selected a wide range of stakeholders with the understanding that not everyone may agree to participate. The input obtained from those who agree to participate will be used to provide feedback about the template to help us develop a template that better meets the needs of stakeholders. The consequences of not collecting feedback from key stakeholders include lack of engagement, low usability, and low adoption of structured reporting for database studies.

This project addresses an important gap in transparent exchange of information. The project directly follows the work from a joint task force between the International Society for Pharmacoepidemiology and International Society for Pharmacoeconomics and Outcomes Research, which produced a catalogue of specific parameters that represent key scientific decisions made when implementing database studies. The principal investigators for this project co-led the joint task force and are unaware of other ongoing efforts that would be duplicative of this project.

2. Intended Use of Information:

We are collecting this information to inform us about the structured reporting template (Appendix B1). To test and refine the reporting template, the investigator will synthesize qualitative feedback from focus groups, including information regarding the clarity, efficiency, and usability of the reporting template.

3. Description of Respondents:

Focus group participants with whom we anticipate engaging (i.e., communicating) during the development of the structured reporting template may include representatives from various organizations, including regulatory bodies, distributed data networks, healthcare delivery systems, scientific journals, professional societies, patient groups, the international network, the pharmaceutical industry, contract research organizations, and other organizations involved in research reporting.

4. Date(s) to Be Conducted and Location(s):

Focus groups will be conducted via phone (teleconference), only, between the months of June through September 2019 (to be scheduled per participants' availability after informed consent is obtained – Appendix C). There will be no physical location for the focus groups. Each focus groups will include the study team members, selected FDA employees, and up to six non-FDA, non-study team member stakeholders, selected based on their scheduling availability. Participants will call into the teleconference at the scheduled dates/times from their preferred location (e.g., office/home). We will not initiate contact of participants until after we receive OMB approval.

5. How the Information is Being Collected:

Brigham and Women's Hospital will gather qualitative information via focus groups, conducted via teleconferences, where participants will be asked to provide feedback about the reporting template.

We will focus specifically on stakeholder feedback regarding:

- a. Usability
- b. Clarity
- c. Efficiency
- d. Effect on ability to evaluate validity of evidence from published database studies or study protocols and reports if the template is used by the authors to report the study
- e. Barriers to use
- f. Suggestions for improvements

6. Number of Focus Groups:

There are two proposed tasks for this collection. The first is a 30-minute session of time, which includes a 5 minutes informed consent and 25 minutes offline review of the structured reporting template and the user guide. Second, each participant will participate in a 90-minute group session. To make the sessions more efficient and to accommodate everyone’s schedule, the research team will schedule 90-minute focus groups with up to 6 participants in each group. Since the focus groups will provide qualitative information, only, statistical significance is not relevant. There is no inference or statistical test of significance being considered in this project based on focus groups. Each person will participate in one focus group. Overall, 120-minute participation time is expected for each person. We plan to contact 8 FDA staff members by email to participate in the focus groups. Their input regarding the template will be solicited during the focus group meetings.

Each focus group will include up to six stakeholders as well as members of the study team. Participants in each group will be selected primarily based on their schedule availability.

7. Amount and Justification for Any Proposed Incentive:

No compensation will be provided.

8. Questions of a Sensitive Nature:

Questions will be limited to the usability/clarity/efficiency of the reporting template, none of which are sensitive in nature.

9. Description of Statistical Methods (i.e., Sample Size & Method of Selection):

The study employs qualitative methods and does not entail the use of any statistical methods.

BURDEN HOUR COMPUTATION (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

Type/Category of Respondent Activity	No. of Respondents	Participation Time (minutes)	Burden (hours)
Informed Consent/Offline Review	34	30	17
Focus Group Session	34	90	51
TOTAL	34	120	68

REQUESTED APPROVAL DATE: July 2019

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