

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CUSTOMER SATISFACTION SURVEYS (0910-0360)

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement.

TITLE OF INFORMATION COLLECTION: Interviews with Applicants and Other External Stakeholders Regarding Use of Patient Experience Data in Regulatory Decision Making

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

The 21st Century Cures Act of 2016 requires FDA to complete and publish an assessment of the Agency's use of patient experience data in regulatory decision making every five years. For the current assessment, FDA's contractor will examine Agency use of patient experience data in the review of NDAs, BLAs, and efficacy supplements received between June 12, 2017 and June 12, 2020 and acted on by February 5, 2021 (about 1,950 applications).

A key part of the assessment will involve collecting qualitative information via interviews with applicants and other external stakeholders (patients, caregivers, healthcare providers, and representatives of research, education, support, and advocacy organizations). The purpose is to obtain feedback about satisfaction with what patient experience data FDA considers in regulatory decision making, satisfaction with how the Agency considers these data in regulatory decision making, satisfaction with how FDA communicates use of these data in regulatory decision making, and suggestions for improvement to better meet the needs of stakeholders. This information is not available through other means.

2. **Intended use of information:**

FDA will use the information to understand the extent to which external stakeholders are satisfied with its use of (and communication about use of) patient experience data in regulatory decision making. This includes understanding how stakeholders view the appropriateness, quality, and clarity of FDA's use of patient experience data. Based on this understanding, FDA will determine whether and how to adjust its use of patient experience data in regulatory decision making (or communication thereof) from an implementation perspective. The data will not be used for the purposes of making policy or regulatory decisions.

3. **Description of respondents:**

The two respondent groups are: (1) applicants with applications received between June 12, 2017 and June 12, 2020 and acted on by February 5, 2021; and (2) other external stakeholders who are interested in this topic, such as patients, caregivers, healthcare providers, and representatives of research, education, support, and advocacy organizations.

FDA's contractor for this work, Eastern Research Group, Inc. (ERG), will perform interviews from 10 applicant companies that represent a variety of company sizes, experience level, and therapeutic areas. Each of 10 interviews will include 1-3 representatives from the applicant company. Representatives will be individuals knowledgeable about collection of patient experience data and inclusion in marketing applications to FDA (e.g., Directors of Regulatory Affairs, Clinical Lead, Global Project Lead, Chief Regulatory Officer).

External stakeholders will include patients, caregivers, healthcare providers, and representatives of research, education, support, and advocacy organizations. Each of 20 interviews will include 1-5 representatives from an array of stakeholder groups and a variety of therapeutic areas. Interviewees will be people with interest in use of patient experience data in drug development and regulatory decision making, along with experience reading published FDA application reviews.

4. Date(s) to be Conducted:

FDA will collect this information between November 2020 and February 2021.

5. How the Information is being collected:

FDA will collect this information through group interviews. FDA has contracted with Eastern Research Group, Inc. (ERG), an independent consulting firm, to perform these interviews via teleconference. Interviews are expected to last 60-90 minutes each. Scripts for the interviews are attached.

6. Confidentiality of Respondents:

The contractor will recruit people, conduct the interviews, and prepare aggregated, anonymized summaries and qualitative analyses for FDA. The contractor will not share any identifying information outside its internal project team.

FDA will know what applicant entities are within scope for these interviews because by definition they have submitted applications to the Agency; FDA will not know which applicant entities ERG contacted, which accepted or declined interviews, or which individuals within the applicant entities participated in interviews. Similarly, FDA will not know what external stakeholders (either organizations or individuals) are interviewed.

All interviews will be voluntary. The interview scripts will include the following text:

“Your participation / nonparticipation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.”

7. Amount and justification for any proposed incentive

No incentive is being offered.

8. Questions of a Sensitive Nature (Data will be kept private to the extent allowed by the law)

No questions of sensitive nature are being asked.

9. Description of Statistical Methods

No statistical methods are being used.

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

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Applicants	30 (= 3 interviewees per applicant company x 10 applicant companies)	90 (max)	45
Non-applicant external stakeholders	100 (= 5 interviewees per group x 20 groups)	90 (max)	150
TOTALS	130	-	195

REQUESTED APPROVAL DATE: November 14, 2020

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