

Summary of Survey
Generic Clearance of Customer Satisfaction
OMB Control No. 0910-0360

Assessment of Physician Applicants' Experiences with FDA's Expanded Access and Compassionate Use Programs

Project Summary: To inform our understanding of physician applicant experiences with the FDA Expanded Access and Compassionate use programs and provide feedback that may lead to program improvements.

FDA/OC/OMPT used the generic 0910-0360, Customer Satisfaction Surveys to inform our understanding of physician applicant experiences with the FDA Expanded Access and Compassionate use programs and provide feedback that may lead to program improvements. The project received OMB approval 12/20/2017.

Problem being investigated:

FDA's Expanded Access and Compassionate use (EA) program provides a process for patients to obtain authorization to use an investigational medical product for treatment use that has not been FDA approved⁴ for use outside of a clinical trial setting. As part of FDA's commitment to continuous operational improvement of the EA program, the Agency commissioned an independent assessment of the EA program that considered stakeholder perspectives from across the healthcare ecosystem. This includes an evaluation of the experiences of physician sponsors who have submitted EA applications; they are key stakeholders and users of this program. They also shoulder the vast majority of the burden of the EA process and the time required was considered critical. The objectives of this survey included (1) evaluate physician applicants' experiences with EA/CU program (e.g., how they found out about the program, ease of use, timeliness, overall satisfaction); (2) assess implications of healthcare provider affiliation and specialty in awareness, expectations, and experience; and (3) to identify healthcare provider perspectives on potential program enhancements and overall feedback on EA program.

Methodology used to collect the data:

Candidate respondents received an email message from McKinsey & Company that identified them as contractors working for FDA and explaining the goal of the survey. It also included a survey consent form. Once a survey consent form was returned via email to McKinsey & Company, respondent was sent a link to the survey. The survey was successfully fielded with 139 respondents.

Burden Imposed:

66/670 burden hours were approved to conduct the survey. This was based on an estimated time of 20 minutes for each of 200 respondents. It is estimated that the burden hours of 139 respondents was 46.3 hours.