

Consent to participate in the study

Title of Project: Focus group and individual interview assessments of knowledge of the Expanded Access and Compassionate Use programs among stakeholders

Researcher: U.S. Food and Drug Administration (FDA) via a contract with a third party research firm

Invitation to participate in the study

FDA is committed to increasing awareness of and knowledge about its Expanded Access and Compassionate Use (EA/CU) programs and the procedures for obtaining access to human investigational drugs (including biologics) and medical devices, and in improving the experiences of users of these programs. FDA will use the qualitative data collected during the stakeholder focus groups and individual interviews to aid in identifying potential areas of improvement that will impact its programs, increase stakeholder understanding of the programs, and facilitate use of the programs when appropriate.

The focus group or individual interview will assess your knowledge, interest, and use of FDA's EA/CU programs.

FDA has contracted with a third-party research firm to perform this work.

Description of your involvement

If you agree to participate in this study, you will be asked about your knowledge, interest, and use of FDA's EA/CU programs. You will not be asked to provide any personally identifiable information (PII) during the focus group session.

Benefits of Participation

FDA's EA/CU programs represent a "last chance" for patients who have no other reasonable medical options; improvements to the program that increase use is a benefit to those patients.

Compensation for Participation

You will not receive compensation for participating in this focus group or interview. You may withdraw your participation at any time.

Confidentiality

Staff at the third-party research firm and the FDA will see the information that you provide. The results of this focus group will be shared with FDA. Should PII be included in the data collection, it will not be attached to any data and not shared with the FDA. Aggregate results may be made public. Individual answers may also be made public (e.g., example responses).

All respondent identification and information are confidential and will be anonymous unless otherwise indicated. 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 your identity and information will remain private to the extent permitted by law.

Voluntary Nature of the Study

Participating in this focus group is completely voluntary. You do not have to answer a question that you do not want to answer. Your participation/non-participation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services.

Storage and Future Use of the Data

The third-party research firm will share the data with the FDA. It will be archived for potential use for the purposes described above. Should PII be included in the data collection, it will not be attached to any data and not shared with the FDA. Aggregate results may be made public. Individual answers may also be made public (e.g., example responses). Your identity and information will remain private to the extent permitted by law.

Contact Information for the Study Team

If you have questions about your rights as a participant or are dissatisfied with any aspect of the focus group, or have questions about the research, you may contact Kate Chavez at Kate.Chavez@fda.hhs.gov or 973 549-6967.

Contact Information for Questions about your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researchers, please call Allison Hoffman at 301-796-9203. Please leave a message with your full name and the name of the study, “Assessment of physician applicants’ experiences with FDA’s Expanded Access and Compassionate Use programs,” and your phone number, beginning with the area code. Someone will return your call as soon as possible.

Consent

By signing below, you are agreeing to be in the study. You should keep a copy of this document for your records, and a copy of your consent form will be kept with the study records.

Be sure that any questions you have about the study have been answered and that you understand what you are being asked to do. You may contact the researcher if you have a question later.

I agree to participate in the study.

Printed Name

Signature

Date