FDA Use of Patient Experience Data in Regulatory Decision Making External Stakeholders Interview Script

October 23, 2020

The study we are conducting is on behalf of the U.S. Food and Drug Administration.

FDA Use of Patient Experience Data in Regulatory Decision Making and Communication About this Use

1. How easily were you able to find information about how FDA uses patient experience data in its reviews of drug applications?

   Probes: How easily were you able to find the documents? How easily were you able to locate information within the documents?

2. In the documents you read, how would you characterize the patient experience data that FDA considered in its drug reviews?

   Probes: How adequate were the types of patient experience data that FDA considered? What is your impression of the quality and completeness of the data? What types of data would you like industry to provide to FDA in their drug applications? What other sources of patient experience data would you like FDA to consider?

3. In the documents you read, to what extent did FDA provide the information you want about ***how*** the Agency uses patient experience data in its drug reviews?

   Probes: What types of information do you want to see? Of the information you saw, what was helpful? What was not helpful, insufficient, or missing?

4. How would you rate the clarity of the information about FDA's use of patient experience data?

   Probes: How understandable was the information? How complete? How logically was it presented?

5. What good practices do you observe in how FDA uses patient experience data in its drug reviews? In communicating ***how*** it uses these data in deciding whether to approve drug applications?

6. What suggestions for improvement can you offer?