Use of Patient Experience Data in Regulatory Decision Making
Applicant Interview Script

October 23, 2020

Paperwork Reduction Act Statement: Public reporting burden for this collection of information is estimated to average 60 to 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Your participation/nonparticipation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The control number for this project is 0910-0360. Send comments regarding this burden estimate or any other aspect of this collection of information to: Food and Drug Administration, Office of Operations, 3WFN, 11601 Landsdown St., North Bethesda, MD 20852.

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

Type of Patient Experience Data Collected and Included in Applications

1. What types of patient experience data do you collect during the IND stage of development? Why these types?

2. What types of patient experience do you include in applications to FDA? Why these types?

3. What other types of patient experience data would you like to collect or include? Why?

4. How clear were FDA's expectations about the types of patient experience data the Agency would like sponsors to include in applications?

   Probes: Did you discuss FDA's expectations or your plans for including patient experience data in any emails, calls, or meetings? Did you consult any FDA guidance related to patient experiences data when designing your study? Did FDA direct you to guidance or other Agency documents?

5. What resources or FDA guidances do you find helpful in collecting or including patient experience data in applications?

6. What other resources would be helpful in collecting or including patient experience data?

7. What challenges do you face in collecting and including patient experience data?

8. What do you see as good practices for collecting and including patient experience data?

9. What suggestions do you have for improving industry collection and inclusion of patient experience data?

FDA Use of Patient Experience Data and Reporting on this Use

10. How would you characterize FDA's use of patient experience data in its reviews and regulatory decision making?

    Probes: What do you think about how FDA factors patient experience data into its reviews and decisions? How much weight the Agency gives these data? How it cites these data in its decisions?

11. What good practices do you observe in FDA's use of patient experience data in its reviews and regulatory decision making?

12. What suggestions for improvement can you offer?

13. How would you characterize FDA's communication about its use of patient experience data in reviews and decisions?

14. What good practices do you observe in FDA's communication about its use of patient experience data?

15. What suggestions for improvement can you offer?