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> *According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-XXXX. The time required to complete this information collection is estimated to average 90 minutes per response, including the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.*

Sponsor Review Process Interview Script

Beginning the Interview

Thank you for taking the time to talk with us today. I am [name] and this is [name(s)], from Eastern Research Group.

> If face-to-face, shake hands.

> If multiple interviewees are present and do not spontaneously introduce themselves, prompt:

> And you are?

 Pleasure to meet you.

> Alternative if sponsor is known to the interviewer: Good to see you.

As part of our independent assessment of the combination product review practices, we would like to ask you about your experiences with the review process for [RFD/Pre-RFD, IND/pre-IND, or NDA/BLA] [application number], [product name].

The purpose of this interview is to obtain your opinions and feedback about the review process for [product name].

This interview should take about an hour to an hour and a half. I will ask questions, and [name(s)] will take notes. ERG will keep your identifying information private. We will share only anonymized results outside our internal project team. We appreciate your participation.

Do you have any questions before we start?

> *After any questions have been addressed, proceed to 'Conducting the Interview'*

Conducting the Interview

1. (For RFDs/pre-RFDs only) What were your reasons for choosing one process (RFD or pre-RFD) over the other?

2. To what extent were available FDA guidances helpful in preparing your submission? What other sources of information, if any, did you find useful? What gaps in information, if any, did you identify?

3. In what ways did you communicate with FDA before submission, and how frequently did you communicate?

4. In what ways did you communicate with FDA during review of the submission, and how frequently did you communicate?

5. In what ways were these communications helpful during the submission and review process? What other resources, if any, would have been helpful?

6. Who was your main FDA contact for the submission, and to what extent did you communicate with other FDA staff?

7. How would you characterize the overall process for this [RFD/pre-RFD/IND/pre-IND/NDA/BLA] (in terms of efficiency, effectiveness, clarity)?

8. (If pre-approval/pre-license inspections were conducted) How would you characterize coordination and communication for the inspection processes?

Experiences with FDA Advice *(if applicable)*

9. When did you receive FDA advice on bridging studies, incorporating human factors, and/or labeling? How would you describe the timeliness and clarity of the advice?

10. Did FDA change its advice at any point? If so, what were the circumstances and impact of the change?

11. Were you able to comply with FDA's advice? If not, what were the circumstances?

Good Practices, Challenges, and Suggestions

12. What practices, if any, did you find particularly helpful during the preparation and/or review of this submission?

13. What challenges, if any, did you encounter for this submission?

14. What suggestions, if any, do you have for improving the submission and review process for combination product [RFDs/pre-RFDs/INDs/pre-INDs/NDAs/BLAs]?

Closing the Interview

Thank you very much for taking the time to talk with us. Your feedback is helpful in giving us a sense of how the combination product review program is working from a real-world perspective. Thanks again.