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Sponsor Interviews: Script

Over the course of the interview, we may refer to one or both of the following guidances published by FDA:

Best Practices for Communication Between IND Sponsors and FDA During Drug Development Guidance for Industry and Review Staff, hereafter referred to as "communications guidance"

and

Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products, hereafter referred to as "meetings guidance."

Overview of IND Communications

To start, let's talk about the communications you have had with FDA review staff for this IND.

1. What types of communications did you have with FDA review staff between September 2018 and now? Over the lifetime of the IND?

   Note: The timeframe of September 2018 to present serves to provide a frame for recent communications. As necessary, reassure interviewees that they do not need to recall exact dates or be certain that their responses reflect communications in exactly that timeframe.

2. How frequently did you have these communications between September 2018 and now? Over the lifetime of the IND)?

3. Who was your main point of contact? Outside of meetings, who else did you communicate with directly?

Experiences with IND Communications

4. How would you characterize the *timeliness* of your communications with FDA review staff? Are the published timelines for meetings appropriate for you? For FDA review staff (based on your experience)?

5. How would you characterize the *clarity* of the communications with FDA reviewer staff?

6. For meetings with FDA review staff, how would you characterize the quality of meeting minutes?

7. How would you characterize the *effectiveness* of your communications (all types) with FDA review staff in resolving questions/issues and enabling you to move forward with product development or decisions?

8. Beyond that, how did the communications influence your drug development strategies for this IND?

9. In your memory, did FDA change its advice on this IND at any point? If so, what were the circumstances and impact of the change? Did FDA give an explanation for the change in advice?

10. In your memory, did FDA's review team for this IND change at any point? If so, what was the impact of the change?

Good Practices, Challenges, and Suggestions

11. What communication practices, if any, did you find particularly helpful for this IND?

12. What communication challenges, if any, did you encounter for this IND?

13. What suggestions, if any, do you have for improving communication practices for INDs?