*OMB Control No.: 0910-xxxx*

*Expiration date: xx/xx/xxxx*

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## Sponsor Survey: Instrument

*Instructions:*

*In completing this survey, please think about your recent Type [A/B/B EOC/C] meeting for IND [number].
All guidelines and requirements referenced in the questions pertain to:*

**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”).

**FDA Guidances**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. For this meeting, the meetings guidance was helpful in understanding:
 | **Strongly Disagree** | **Disagree** | **Neutral** | **Agree** | **Strongly Agree** | **Don’t Know** |
| Requirements for the meeting request. | O | O | O | O | O | O |
| Requirements for the meeting package. | O | O | O | O | O | O |
| What to expect during the meeting. | O | O | O | O | O | O |

2. Comments on the meeting process:

|  |
| --- |
|   |

**Before the Meeting**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 3. In preparing for this meeting, we found that: | **Strongly Disagree** | **Disagree** | **Neutral** | **Agree** | **Strongly Agree** | **Don’t Know** |
| The required meeting package format was effective for communicating our questions/issues to FDA. | O | O | O | O | O | O |
| FDA’s preliminary comments were responsive to our questions/issues. | O | O | O | O | O | O |
| FDA’s preliminary comments clearly distinguished between regulatory requirements and advice. | O | O | O | O | O | O |
| Where appropriate, FDA’s preliminary comments directed us to specific regulations or guidance. | O | O | O | O | O | O |

4. (Optional) Comments on communication processes and practices *before* the meeting:

|  |
| --- |
|  |

**The Meeting**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 5. From our perspective: | **Strongly Disagree** | **Disagree** | **Neutral** | **Agree** | **Strongly Agree** | **Don’t Know** |
| FDA staff who we requested, needed to answer our questions, were present. | O | O | O | O | O | O |
| FDA clearly distinguished between regulatory requirements and advice. | O | O | O | O | O | O |
| FDA directed us to specific regulations or guidance where appropriate. | O | O | O | O | O | O |
| This meeting was an effective means of addressing our questions/issues. | O | O | O | O | O | O |

6. (Optional) Comments on communication processes and practices *during* the meeting:

|  |
| --- |
|  |

**Other Feedback**

1. What good practices contributed to a positive meeting planning and meeting experience?

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| --- |
|  |

1. What challenges hindered the efficiency or effectiveness of the meeting process and meeting?

|  |
| --- |
|  |

1. What suggestions, if any, do you have for improving communication practices for IND meetings?

|  |
| --- |
|  |

1. (Optional) Other comments related to the meeting:

|  |
| --- |
|  |