

## Sponsor Survey: Protocol

Eastern Research Group, Inc. (ERG) is conducting an independent assessment of U.S. Food and Drug Administration (FDA) review staff and sponsor staff communication practices for active commercial Investigational New Drugs (INDs) in the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). As part of the assessment, ERG is conducting a survey of sponsors for a sample of 150 active commercial INDs with activity during a one-year period. ERG will administer a survey for every formal meeting between the IND sponsor and FDA review team to obtain feedback about meeting practices.

### ERG Pre-Work

ERG has assigned Marc Goldstein to serve as ERG's task coordinator, with Jason Hsiao serving as backup coordinator as needed. Upon establishing the sample of active commercial INDs, the task coordinator will monitor the INDs for scheduled Type A, B, B (End Of Phase), and C meetings. Upon identifying such a meeting, the task coordinator will assign an ERG staff member to conduct the post-meeting survey.

### FDA Pre-Work

When the IND sample is established or updated, FDA Office of Program and Strategic Analysis (OPSA) staff will notify active commercial IND sponsors in the sample that they might receive a survey or interview request from ERG.

I am sending this notice as the FDA Office of Program and Strategic Analysis (OPSA) project manager overseeing an independent contractor assessment of FDA-sponsor communication practices during the IND stage of drug development.

This notice is to inform you that the independent contractor, Eastern Research Group, Inc. (ERG), might contact you to request feedback about your interactions with FDA review staff. Specifically, ERG might:

- *For Type A, B, B (EOP), and C meetings with FDA review staff: Attend the meetings as silent observers.*
- *After Type A, B, B (EOP), and C meetings with FDA review staff: Send a survey to obtain feedback about your experience with a meeting.*
- *After a period of time during which you and FDA review staff have engaged in communications about your IND: Send an interview request to obtain broader feedback about your experience with all types of communications (telephone, email, meetings) with FDA review staff.*

This assessment is part of FDA's commitment to industry for PDUFA VI. Your participation is voluntary. If you choose to participate, ERG will keep your responses private, sharing only anonymized aggregated summaries with FDA. Your feedback will be valuable in informing ERG's assessment of current IND communication practices. FDA will publish the assessment report on the Agency's website no later than the end of FY 2020.

## Conducting Post-Meeting Surveys

When the ERG task coordinator identifies an in-scope IND meeting, the staff member assigned to the meeting will:

- 1) Identify the primary contact for the IND sponsor.
- 2) Send an email with a survey link to the sponsor representative.
- 3) Monitor the survey for a response.
- 4) If the sponsor does not respond within one week, send a reminder email with the survey link.
- 5) If the sponsor does not respond within one week, call the sponsor representative to request a response or determine whether the survey should be sent to an alternative sponsor representative.

## QA/QC

To ensure the quality and consistency of survey processing, the ERG task coordinator will:

- 1) Review this protocol and good survey practices with all members of the ERG assessment team.
- 2) Review all communications and survey processing for the first five surveys and every twentieth survey thereafter.
- 3) QC the survey database containing survey responses.

## Email/Call Scripts

ERG will send this request to sponsors requesting their participation in a post-meeting survey. If ERG receives no response after one week, ERG will send the same message again with “Second request” appended to the subject line. If ERG receives no response after one more week, ERG will call the sponsor using the script shown below.

### **Sponsor Survey Request [by email, using ERG email address]**

*Subject line:* PDUFA VI IND Communications Assessment: Survey request for [IND name]

Dear [first and last name of contact person],

I am contacting you to request your participation in an online survey about your experience with a [date] Type [type] meeting with FDA review staff on [IND name], IND [#]. This survey should take about 10 minutes to complete:

[survey link]

As a part of FDA’s commitments for PDUFA VI, FDA has enlisted Eastern Research Group, Inc. (ERG) to conduct an independent assessment of FDA reviewer-sponsor communication practices during the IND stage of drug development. An important part of the assessment is feedback from sponsors regarding their experiences with Type A, B, B (EOP), and C meetings. Your responses will help us learn what aspects of meetings are going well and what can be improved. We will keep your individual responses private, sharing only anonymized aggregated summaries of results with FDA and the public (in our assessment report, which FDA will publish on the Agency’s public website).

We ask you to complete this survey by [date=current date + 7 days]. If you have any questions about the survey, please feel free to contact me. Thank you!

Best regards,

[Name]

[Contact information: email and phone]

I am [name] with ERG, the contractor conducting an independent assessment of PDUFA VI IND communication practices for FDA. I am following up on a request I emailed asking you to participate in a survey about your [date] Type [type] meeting with FDA review staff on [IND name], IND [#].

Do you remember receiving this request?

If yes: Are you able to complete the survey by [date]?

If yes: Would you like me to send you the survey link again?

If yes: I will do that right after this call. Thank you for completing the survey!

If no: Thank for you completing the survey!

If no: Would it be appropriate for someone else to complete the survey?

If yes: [take name and contact information]. Thank you very much for your help.

If no: Would you like to decline participation in this survey?

If yes: Thank you for letting me know. Have a good day!

If no: How would you like to proceed with the survey?

[Respond accordingly]

If no: I will send the survey link to you right now. Can you complete the survey by [date]?

If yes: Thank you for completing the survey!

If no: Would it be appropriate for someone else to complete the survey?

[Continue as above]

If sponsor agrees to take survey: This survey is voluntary, and ERG will keep your responses private. The email I sent includes more information about the voluntary nature of the survey.

Thank you, and have a great day.