

Sponsor Interviews: 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 interviews with sponsors for a sample of 150 active commercial INDs that have activity during a one-year period. ERG will interview IND sponsors after a period of telephone/email communications and meetings between sponsors and FDA review staff.

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 FDA review staff-sponsor communications activity. Upon identifying an IND with communications activity over a period of at least six months, the task coordinator will assign an ERG staff member to conduct the interview.

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 Interviews

When the ERG task coordinator identifies an IND ready for a sponsor interview, the staff member assigned to the meeting will:

- 1) Identify the primary contact for the IND sponsor.
- 2) Request an interview:
 - ✓ Email an interview request to the sponsor representative.
 - ✓ Plan the date, time, and location for a 60-minute interview. ERG will conduct the interview by telephone or face-to-face, depending on the sponsor's preference.
 - ✓ Identify up to three sponsor representatives to be present, such as the Regulatory Program Lead, Clinical Lead, and/or Global Project Lead.
 - ✓ Send an interview confirmation, with all logistics specified, to interviewee(s).
 - ✓ Send a meeting reminder 24-48 hours before the interview.
- 3) If the sponsor does not respond to the interview request within one week, send a second request. If the sponsor does not respond to the second request within one week, call the sponsor representative to request the interview.

ERG staff assigned to the interview will implement the interview as follows:

- **Interviewer:** Conduct the interview in accordance with the script and good interview practices for engaging interviewees while remaining neutral and objective. This includes probing for insights about the underlying reasons for specific interviewee feedback.
- **Note-taker(s):** Record interviewee responses throughout the interview. After the interview, review this documentation with the interviewer and additional note-taker (where applicable) to ensure the adequacy and accuracy of the notes. Enter notes into the Interview Log. Place hard copy instrument/notes in a secure filing cabinet at the onsite ERG office.

ERG will not share identifying information or IND-specific interview content outside the internal project team. ERG will report only anonymized aggregated results and findings in the assessment report. Interviews should last no longer than 90 minutes.

QA/QC

To ensure the quality and consistency of interviews, ERG will assign at least two people to conduct the interviews. These staff will:

- 1) Designate an interviewer and at least one note-taker.
- 2) After the interview, compare notes on responses to identify any differences.
- 3) Discuss any differences with the ERG project team, decide on a resolution, and enter an agreed-upon set of responses into the tracker tool.

- 4) Note any differences found and resolution agreed upon in a Comments field in the tracker tool.

Email/Call Scripts

ERG will send this request to schedule interviews with sponsors using their ERG email account. If there is no response after seven calendar days, ERG will send the same message again with "Second request" appended to the subject line. If there is no response after another seven calendar days, ERG will call the sponsor using the script below.

Sponsor Interview Request [by email, using ERG email address]

Subject line: PDUFA VI IND Communications Assessment: Interview request regarding [IND name]

Dear [first and last name of contact person],

As part of FDA's commitments for PDUFA VI, the agency has asked Eastern Research Group, Inc. (ERG) to conduct an independent assessment of FDA review staff-sponsor communication practices during the IND stage of drug development. For that assessment, I am contacting you to request an interview to discuss your experience with communications with FDA review staff for [IND name], IND [#].

During the interview, we will ask about your experiences with all types of communications with FDA review staff, including telephone calls and emails in addition to meetings.

Please choose an interview date and time (in 60-minute blocks):

1. [Date/time block 1]
2. [Date/time block 2]
3. [Date/time block 3]
4. [Date/time block 4]
5. Other (please specify): _____

Please choose a location from the following options:

1. FDA's White Oak Campus in Silver Spring, MD (we will reserve a conference room)
2. Telephone interview (please specify telephone number): _____

Please identify the people (up to three) who will participate in the interview:

1. _____ (Name, title/role)
2. _____ (Name, title/role)
3. _____ (Name, title/role)

Thank you for your attention. I will follow up with a meeting confirmation with the date, time, and location of our interview. If you have any questions in the meantime or need to reschedule, please feel free to contact me.

Best regards,

[Name]

[Contact information: email and phone]

--

Eastern Research Group, Inc. (ERG) is the contractor conducting an independent assessment of FDA reviewer staff-sponsor communication practices during the IND stage of drug development. An important part of the assessment is feedback from sponsors regarding their experiences with IND-stage communications with FDA. Your responses will help us learn what aspects of these communications 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.

Sponsor Interview Request (phone call after second non-response)

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 an interview about your experience communicating with FDA review staff about [IND name], IND [#].

Are you able to participate in an interview?

If yes: What date and time would work best for you? Would you like to meet onsite at FDA's Silver Spring campus or talk by teleconference? Who will participate in the interview? We can accommodate up to three people from your company.

[Arrange logistics]

I will follow up with an interview confirmation via email with the date, time, and location of our interview. If you have any questions in the meantime or need to reschedule, please feel free to contact me at [insert email] or [insert phone number].

If no: Should I talk with someone else about participating in an interview?

If yes: Proceed with that person as above.

If no: Would you like to decline participation in this interview? [Respond accordingly.]

Thank you, and have a great day!

For sponsors who agree to an interview, ERG will send this interview confirmation.

Interview Confirmation [by email, using ERG email address]

Subject line: Confirmation: PDUFA VI IND Communications Assessment Interview regarding [IND name]

Dear [first and last name of interviewee(s)],

This is confirmation of our upcoming interview about your communication experiences with FDA review staff regarding [IND name], IND [#].

When: [Day], [Date], [Time]

Where: [Location]

Who: [Name(s), Title(s)]

Thank you for your participation. We look forward to speaking with you.

Best regards,

[Name]

[Contact information: email and phone]

Eastern Research Group, Inc. (ERG) is the contractor conducting an independent assessment of FDA review staff-sponsor communication practices during the IND stage of drug development. An important part of the assessment is feedback from sponsors regarding their experiences with IND-stage communications with FDA. Your responses will help us learn what aspects of these communications 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).

ERG will send this meeting reminder 24-48 hours before the interview.

Interview Reminder [by email, using ERG email address]

Subject line: Reminder: PDUFA VI IND Communications Assessment Interview regarding [IND name]

Dear [first and last name of interviewee(s)],

This is a reminder for our upcoming interview about your communication experiences with FDA review staff regarding [IND name], IND [#].

When: [Day], [Date], [Time]

Where: [Confirmed location]

Who: [Name(s), Title(s)]

Thank you for your participation. We look forward to speaking with you.

Best regards,

[Name]

[Contact information: email and phone]

Eastern Research Group, Inc. (ERG) is the contractor conducting an independent assessment of FDA reviewer staff-sponsor communication practices during the IND stage of drug development. An important part of the assessment is feedback from sponsors regarding their experiences with IND-stage communications with FDA. Your responses will help us learn what aspects of these communications 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).

If sponsors request the interview questions, ERG will attach the prepared PDF file with general interview questions and include the following statement in the response:

Sponsor Request for Interview Questions

[Attach "Interview Questions – Sponsor Request" document]

"Please note that we do not ask or expect you to spend time preparing for this interview. Nevertheless, we can provide our interview questions (see attachment) upon request."