Sponsor Interviews: Data Collection Protocol

Eastern Research Group, Inc. (ERG) is conducting an independent assessment of U.S. Food and Drug Administration (FDA) combination product review practices for Requests for Designations (RFDs), Pre-RFDs, Investigational New Drug (IND) applications, Pre-INDs, New Drug Applications (NDAs), and Biologics License Applications (BLAs) in the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). As part of this assessment, ERG is conducting interviews with sponsors for two samples as follows:

- 50 RFDs/Pre-RFDs
- 67 combination product INDs/Pre-INDs and 43 combination product NDAs/BLAs

During this time, ERG will interview sponsors after the agency responds to a RFD/Pre-RFD or IND/Pre-IND or acts on a NDA/BLA.

ERG Pre-Work

ERG has assigned Christopher Sese to serve as ERG's task coordinator, with Hannah Busey serving as backup coordinator as needed. During the data collection period, the task coordinator will build samples of RFD/pre-RFDs, IND/pre-INDs, and NDAs/BLAs according to the sampling methodology established in the Detailed Evaluation Plan. Upon identifying an application with an FDA decision or response the task coordinator will assign an ERG staff member to conduct interviews. To the extent possible, the task coordinator will assign ERG staff with knowledge of the application. The task coordinator will also assign one or more ERG staff members(s) to act as note-taker(s) during the interviews.

During each interview, ERG will ask interviewees about their experience with the combination product review process for the application, focusing on communication/coordination, completeness, effectiveness, and efficiency. ERG will not expect interviewees to prepare in advance.

FDA Pre-Work

Each month, as ERG builds the three samples, FDA Office of Program & Strategic Analysis (OPSA) staff will send notices to new sponsors in the sample that ERG might contact them for an interview.

Email Notice to Sponsors

Subject line: Notice of contractor request for interview

I am sending this notice as the FDA Office of Program and Strategic Analysis (OPSA) project manager overseeing an independent contractor assessment of combination product review practices.

This notice is to inform you that an independent contractor, Eastern Research Group, Inc. (ERG), is conducting an assessment of combination product review practices. As part of that assessment, ERG might send you a request to participate in an interview to obtain feedback about your experience with FDA during the submission and review process.

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. ERG has signed a non-disclosure agreement and will not disclose any identifying information to anyone outside their project team. Your feedback will be valuable in informing ERG's assessment of current combination product review practices.

Conducting the Interviews

When an ERG task coordinator identifies an RFD/Pre-RFD, IND/Pre-IND, or NDA/BLA ready for interviews, the staff member assigned to the interview will:

1) Identify the contact person for each interview (sponsor main contact).

2) Request an interview:

   - ✓ Summarize purpose of interview and topics to be covered.
   - ✓ Email an interview request.
   - ✓ Send an interview confirmation, with all logistics specified, to interviewee(s).
   - ✓ Send a formal meeting invitation via Outlook to interviewee(s).
   - ✓ Complete an Interview Information Sheet for the interview.
   - ✓ Send a meeting reminder 24-48 hours before the interview.

3) If sponsor staff do not respond to the interview request within one week, send a second request.

Email/call scripts appear at the end of this protocol. 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 application 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 the interviews, notes, and general conduct, ERG will assign two note-takers to the first five interviews and every twentieth thereafter. ERG staff assigned to an interview will:

1) Designate an interviewer and observers/note-takers.
2) After the interview, compare notes on responses to identify any differences.
3) Discuss any differences with the ERG team, decide on a resolution, and enter an agreed-upon set of responses.
4) Note any differences found and the resolution agreed upon in a Comments field of the tracker tool.
5) Modify the coding guide if necessary.

Email/Call Scripts

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

Subject line: PDUFA VI Combination Product Review Practices Assessment: Interview request regarding [product name]

Dear [first and last name of contact person],

I am an analyst from Eastern Research Group, Inc. (ERG) contacting you to request an interview to discuss your experience with the review process for [product name]. ERG is the contractor conducting a third-party assessment of combination product review practices in accordance with FDA's commitments for the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI).

During the interview, we will ask about your experiences with combination product submissions, reviews, and communications with FDA.

Please choose an interview date and time (in 90-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. Telephone interview (please specify telephone number): _____
2. FDA's White Oak Campus in Silver Spring, MD (we will reserve a conference room)
3. Other location near Silver Spring, MD (please specify): _____

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 combination product review practices under PDUFA VI. An important part of the assessment is feedback from sponsors regarding their experiences. Your responses will help us learn what aspects of the combination product review processes 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 there is no response after another seven calendar days, ERG will call the sponsor using the script below.

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

I am [name] with ERG, the contractor conducting an independent assessment of combination product review practices in accordance with FDA's commitments for PDUFA VI. I am following up on a request I emailed asking you to participate in an interview about your experience with the review process for [product name].

Are you able to participate in an interview?

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

[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 Combination Product Review Practices Assessment: Interview regarding [product name]

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

This is confirmation of our upcoming interview about your experience with the review process for [product name].

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 combination product review practices under PDUFA VI. An important part of the assessment is feedback from sponsors regarding their experiences. Your responses will help us learn what aspects of the combination product review processes 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 Combination Product Review Practices Assessment Interview regarding [product name]

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

This is a reminder for our upcoming interview about your experiences with the review process for

[product name].

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 combination product review practices under PDUFA VI. An important part of the assessment is feedback from sponsors regarding their experiences. Your responses will help us learn what aspects of the combination product review processes 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."