

Protocol for Conducting Post-Action Interviews with Sponsors

Eastern Research Group, Inc. (ERG) is conducting an independent assessment of the impact of the PDUFA V Program for Enhanced Review Transparency and Communication on NME NDA and original BLA reviews ('the Program'). As part of the assessment, ERG is conducting interviews with sponsors after Program applications have been reviewed by FDA and receive a first cycle action. For each in-scope application, ERG will conduct interviews with sponsor designees, such as the Regulatory Program Lead, Clinical Lead, and/or Global Project Lead. No more than three individuals will be interviewed per application.

ERG Pre-Work

ERG has assigned Patrick Zhou to serve as ERG's task coordinator, with So Hyun Kim serving as backup coordinator as needed. The task coordinator will maintain a list of Program applications that have received a first-cycle action of Complete Response (CR) or Approval (AP), and a separate list of applications that received an action of Refuse-To-File (RTF) or Withdrawal (WD) without a resubmission. ERG will confirm the accuracy of our list of in-scope applications in three ways:

- Via weekly status checks with the Office of Planning and Analysis (OPA).
- By consulting the Document Archiving, Reporting and Regulatory Tracking System (DARRTS) and the Regulatory Management System for Biologics License Applications (RMS-BLA) within three days of the end of each month to verify that all in-scope applications have been accounted for in ERG's Program Evaluation Tracking Tool (PETT).
- By consulting the Data Analysis Search Host (DASH) within three days of the end of each month to verify that all in-scope applications have been accounted for in PETT.

When an in-scope application receives a first-cycle FDA action, the task coordinator will assign an ERG staff member to schedule and conduct post-action interviews and one or more additional ERG staff member(s) to act as note-taker(s) during the interview. To the extent possible, the task coordinator will assign the interview to ERG staff with previous knowledge of the application (i.e., the staff responsible for observing and evaluating application meetings and milestones).

FDA Pre-Work

FDA will inform sponsors that ERG will contact them after first-cycle actions under the Program to schedule an interview. This will be done systematically (e.g., by placing the text box below in the official action letter).

Notice of Contractor Request for Interview

FDA has contracted with Eastern Research Group, Inc. (ERG) to conduct an independent interim and final assessment of the Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs under PDUFA V ('the Program'). The PDUFA V Commitment Letter¹ states that these assessments will include interviews with applicants following FDA action on applications reviewed in the Program. The purpose of the interview is to better understand applicant experiences with the Program and its ability to improve transparency and communication during FDA review.

You will be contacted by ERG to schedule the interview following this action on your application. Your responses during the interview will be confidential with respect to the FDA review team. ERG has signed a non-disclosure agreement and will not disclose any identifying information to anyone outside their project team. They will report only anonymized results and findings in the interim and final assessments. Members of the FDA review team will be interviewed by ERG separately. While your participation in the interview is voluntary, your feedback will be helpful to these assessments.

Public reporting burden for this collection of information is estimated to average 60-90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other suggestions for reducing this burden to Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Drive, PI50-400B, Rockville, MD 20850, 301-796-7726, Ila.Mizrachi@fda.hhs.gov.

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Post-Action Interview Scheduling

To schedule post-action interviews, ERG's assigned staff will:

- 1) Contact the FDA RPM to confirm who the appropriate sponsor contact is for the application.
- 2) Contact the sponsor within seven calendar days of the action letter date (or within seven calendar days of ERG being notified that the application has received an FDA action) to schedule an interview:
 - ✓ Summarize purpose of interview and topics to be covered.
 - ✓ Plan date, time, and location for face-to-face interview. If necessary (e.g., if sponsor is not local), ERG will conduct the interview by telephone.
 - ✓ Identify up to three sponsor representatives to be present, such as the Regulatory Program Lead, Clinical Lead, and/or Global Project Lead.
 - ✓ Complete a Post-Action Interview Information Sheet for the interview.
 - ✓ Send a formal meeting invitation to interviewee(s).

¹ <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>

- ✓ Send a meeting reminder 24-48 hours before the interview.

Conducting the Interviews

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

Interviewer: Conduct the interviews in accordance with the guide/script for interviewing sponsors – and in accordance with 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: The interviewer will read rating-scale questions as written. For open-ended questions, the interviewer may use discretion in following up on interviewee statements, so the interview might not proceed linearly as scripted.

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. Record responses in PETT and place hard copy instrument in a secure filing cabinet at the onsite ERG office.

ERG will not share identifying information or application-specific interview content with the FDA review team. As appropriate, findings from interviews might be used to implement targeted modifications to the Program to improve the likelihood of its success. ERG will report only anonymized results and findings in the interim and final assessments. Interviews should last no longer than ninety minutes.

QA/QC

To ensure the quality and consistency of our post-action interviews, ERG will assign two note-takers to the first ten interviews and one thereafter, in addition to the interviewer. 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 Program Evaluation team, decide on a resolution, clarify the coding guide accordingly (if necessary), and enter an agreed-upon set of responses into PETT.
- 4) Note any differences found and resolution agreed upon in a Comments field in PETT.

Attachment

ERG will send this request to schedule interviews with sponsors. When a second attempt is needed, ERG will send the same message again with “Second request” appended to the subject line.

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

Subject line: PDUFA V NME Program: Interview request regarding [trade name]

Dear [first and last name of contact person],

I am contacting you to request an interview to discuss your experience regarding [trade name], NDA/BLA [application #], reviewed under the PDUFA V Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs (“The Program”).

Eastern Research Group, Inc. (ERG) is the contractor conducting an independent assessment of the Program. An important part of the assessment, as outlined in the PDUFA V Commitment Letter, is feedback from the FDA review team and applicants regarding the Program. These separate interviews are scheduled after FDA issues a first-cycle action for applications reviewed under the Program. Your participation in an interview is voluntary. ERG will keep identifying information of individual responses strictly confidential.

During the interview, you will be asked about your experience with the review process for your application, practices that improved review transparency, practices that improved communication, as well as any challenges experienced during review of your application in the Program. Your responses will help identify practices that could improve the likelihood of success of the Program.

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 location from the following:

1. FDA’s White Oak Campus in Silver Spring, MD (we will reserve a conference room)
2. [TBD: “Neutral” off-campus location or sponsor’s office if local]
3. Other local location (please specify): _____
4. Telephone interview (please specify telephone number): _____

Optional: Please identify any additional or alternate company staff you would like included in the interview; up to three individuals will be interviewed :

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

Thank you for your attention. I will follow up with a meeting invitation 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]

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When needed, ERG will use this script to request sponsor interviews by phone.

Sponsor Interview Request [by phone]

My name is [name] and I am following up on the emails I sent requesting an interview to discuss your experience regarding [trade name] reviewed under the PDUFA V Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs.

Does sponsor acknowledge emails?

Yes: When would be a good time for an interview?

[If the sponsor does not suggest times, ERG will propose three sets of dates and times.]

No: Eastern Research Group, Inc. (ERG) is the contractor conducting an independent assessment of the Program for reviewing NME NDAs and original BLAs under PDUFA V. We are interviewing sponsors after FDA issues first-cycle actions. Participation is voluntary, and ERG keeps identifying information for individual responses strictly confidential. During the interview, I will ask you about your experience with the review process, practices that improved review transparency, practices that improved communication, and any challenges experienced during review of your application in the Program. Your responses will help identify practices that could improve the likelihood of success of the Program. When would be a good time for an interview?

Is sponsor willing to schedule an interview?

Yes: Thank you very much. Would it be convenient to meet in or around Silver Spring, Maryland, or shall we talk by phone?

Would you like me to include anyone else from your company in the interview? To ensure the efficiency of the interview, we are interested in interviewing up to three individuals as a group for up to 90 minutes.

Yes: Can you please provide the interviewees' contact information? I will follow up with a meeting invitation 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. [Contact information: email and phone]

No: I will follow up with a meeting invitation 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. [Contact information: email and phone]

I'd like to read the standard government statement about the voluntary nature of this interview:

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No: Thanks anyway. I appreciate your time.

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

Meeting Reminder [sent using ERG email address]

Subject line: Reminder: PDUFA V NME Program Interview regarding [trade name]

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

This is a reminder for our upcoming interview about the review of [trade name], NDA/BLA [application #], reviewed under the PDUFA V NME Program:

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]

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