BRF Interview Guide: External Stakeholders

Beginning the Interview

Thank you for taking the time to talk with us today. I am [name] and this is [name(s)], from Eastern Research Group. It's a pleasure to meet you.

As part of our assessment of the Benefit-Risk Framework (BRF), we would like to ask you about your experiences with its use in reviews of [therapeutic area] drugs and biologics, such as [established name(s)].

The purpose of this interview is to obtain your opinions and feedback about the clarity, understandability, and usefulness of the BRF in understanding the reasoning underlying FDA's regulatory decisions. We are not evaluating any drug/biologic applications or the performance of any individual FDA staff members.

This interview should take about an hour to an hour and a half. I will ask questions, and [name(s)] will take notes. ERG will keep your identifying information confidential. We will share only anonymized results outside our internal project team. Here are standard government statements about the voluntary and confidential nature of this information collection:

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 ***Sara Eggers,*** *Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, 51-1145, Silver Spring, MD 20993, 301-796-4904, Sara.Eggers@fda.hhs.gov. Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subjected to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is OMB Control Number 0910-0360.*

Your participation / nonparticipation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.

Do you have any questions before we start?

After any questions have been addressed, proceed to 'Conducting the Interview.'

Conducting the Interview

I am going to ask you about the clarity, understandability, and usefulness of BRFs prepared for [therapeutic area] drugs and biologics. Please feel free to ask me to clarify if anything is unclear.

[Questions]

Closing the Interview

Thank you very much for taking the time to talk with us. Your feedback is very helpful in giving us a sense of how implementation of the BRF is working from a real-world perspective. Thanks again.