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SMALL GROUP DISCUSSION GUIDE: EXTERNAL STAKEHOLDERS AND APPLICANTS

BENEFIT-RISK FRAMEWORK IMPLEMENTATION EVALUATION

OMB Control No: 0910-0697 Expiration Date: 12/31/2023

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0697. The time required to complete this information collection is estimated to average 90 minutes, which will include time to review the BRF and participate in the discussion.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.

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.

The study we are conducting is on behalf of the U.S. Food and Drug Administration (FDA).

Introduction and Objectives

Under the sixth authorization of the Prescription Drug User Fee Act, or PDUFA VI, FDA committed to continuing the implementation of the Benefit-Risk Framework into review documentation processes. The Benefit-Risk Framework is FDA's framework to assess benefits and risks of new drugs and biologics—it was developed to improve the consistency and clarity of benefit-risk assessment during the pre-market review process. As a part of this commitment, FDA contracted Booz Allen to conduct an independent evaluation of its Benefit-Risk Framework (BRF). This includes assessing the Benefit-Risk Framework's clarity, understandability, and usefulness as a communication tool for FDA's external stakeholders. With that, the objectives are to:

1. Obtain your insights on the **clarity** and **understandability** of the Benefit-Risk Framework
2. Discuss how you would rate and assess the **usefulness** of the Benefit-Risk Framework
3. Identify how the Benefit-Risk Framework has been used and ways to which it could be adjusted to increase its usefulness

As part of our assessment of the Benefit-Risk Framework, 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)].

This discussion should take about an hour to an hour and a half. Booz Allen will keep your identifying information confidential. We will share only anonymized results outside our internal project team.

[Applicants only] Please state your title and what about FDA's benefit-risk assessment is relevant to your role or otherwise of interest to you?

Discussion Questions

Q1. Do you have any general comments about Benefit-Risk Framework(s) that you've seen that you would like to offer before I ask specific questions?

Understandability: Discussion around how understandable the logic and rationale were in the Benefit-Risk Framework. For the purposes of this discussion, we are defining "understandable" as whether you feel that FDA logically presented the key points in the Benefit-Risk Framework(s) and provided a clear rationale underlying the decision.

Q2. Did you get a chance to read the Benefit-Risk Framework(s) in the review memo we sent prior to this discussion?
   a. What were the biggest "takeaways" for you?
   b. Did anything in the Benefit-Risk Framework(s) surprise you?
   c. After reading the Benefit-Risk Framework(s), did you have any further questions about how FDA came to its decisions?

Q3. In what ways is the content understandable?

Q4. In what ways can the understandability be improved?

Q5. On a scale of 1 to 4, how would you rate the understandability of the content presented in the Benefit-Risk Framework(s) you have seen, where 1 is not at all understandable and 4 is very understandable?

Clarity: Discussion about how clearly you felt the information and key points in the Benefit-Risk Framework(s) were stated. For the purposes of this discussion, we are defining "clear" as key points are stated explicitly, parsed, and sequenced appropriately, and grouped logically in a manner to which you can read the content easily.

Q6. Is the content presented clearly? If so in what ways?

Q7. In what ways can the clarity be improved?

Q8. On a scale of 1 to 4, how would you rate the clarity of the Benefit-Risk Framework(s) you have seen, where 1 is not at all clear and 4 is very clear?

Usefulness: Discussion about how you use (or would like to use) the BRF and the extent to which the BRF has been useful for these purposes.

Q9. How have you used or how do you plan to use Benefit-Risk Framework(s)?
   a. How useful is the Benefit-Risk Framework(s) for these purposes?

Q10. How can the usefulness of Benefit-Risk Framework(s) be improved?

Q11. How else would you like to use the Benefit-Risk Framework(s)?
   a. How would the Benefit-Risk Framework(s) need to be adjusted to accommodate these uses?

Q12. On a scale of 1 to 4, how would you rate the usefulness of Benefit-Risk Framework(s) for your purposes, where 1 is not at all useful and 4 is very useful?

Q13. Is there anything else that you would like to add about the Benefit-Risk Framework(s) that we haven't covered today?