TAP Assessment ICR Interview Scripts and Questions for External Stakeholders

External Stakeholder Script

Thank you for joining this meeting. My name is [Interviewer's Name], and I am with Eagle Hill Consulting. I am joined by my colleague, [Co-Interviewer's Name]. We are working with FDA to gather feedback from Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot participants. I will be leading the discussion, and [Co-Interviewer's Name] will be taking notes. Before we jump into the discussion, I will give a rough overview of our objectives and then cover a few logistical notes.

The purpose of this interview is to better understand your participation in the TAP Pilot and the impact the Pilot has had on your organization. You might have taken a recent survey related to the TAP Pilot, and in this follow-up discussion we would like to learn more about your experiences in the Pilot, and what you have gleaned as a Pilot participant.

A few logistical notes: please be aware that this discussion in voluntary. This discussion in confidential and nothing you say will be attributed back to you. Also, this meeting is intended to be more of a discussion than an interview, so we encourage you to share your thoughts as they come to mind. Do you have any questions related to the purpose of this meeting before we jump into the discussion?

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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-NEW. The time required to complete this information collection is estimated to average 60 minutes per interview, including the time for reviewing instructions and completing 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.

External Stakeholder Questions

1. We gather that you had [Number and Type of Interactions] with [Sponsors]. Tell me more about those interactions.
    a. How did the facilitation through introductions made by FDA impact your experience with these sponsors?
    b. Please describe how you collaborated among sponsors in these interactions.
    c. What would you do differently, if anything, to make interactions more valuable?
    d. For interactions with sponsors introduced by FDA, what could the sponsor do differently, if anything, to make interactions more valuable?
    e. What could FDA do differently, if anything, to make interactions more valuable?
    f. As you began your participation in the TAP Pilot, how helpful did you find the orientation and supporting materials?
2. You [agreed/disagreed] in the survey that the TAP Pilot was a value-add. Why is that?
    a. Which aspects of the Pilot were particularly valuable to your organization? What factors contributed to an interaction being valuable? Can you give an example?

    b. Which aspects were less valuable?
3. Tell me more about your time commitment to the TAP Pilot. Did your time commitment remain consistent or change over the course of the Pilot?
4. We see in your survey results that you noted that participating in the TAP Pilot helped your organization achieve [Relationship building with sponsors/Relationship building with FDA/Improved understanding of the pre-market medical device review process/Increased awareness of emerging technologies in medicine/Greater influence in the device development process/Other]. Could you elaborate on how the TAP Pilot helped you achieve this?
    a. What new information did the TAP Pilot provide your organization that helped you achieve this?
5. Would you recommend participating in the TAP Pilot to your colleagues? Why or why not?
6. If you had a magic wand, and could change anything about the TAP Pilot, what would you change? Why?
7. Is there any additional information you believe would be valuable for us to know?