

## TAP Assessment ICR Interview Scripts and Questions for Sponsors

### Sponsor 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 discussion is to better understand your participation in the TAP Pilot and the how the Pilot has had on your organization, your strategic decision-making, and the future of your device. 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 is voluntary. This discussion is 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?*

*Paperwork Reduction Act Statement:*

*OMB Control No. 0910-NEW*

*Expiration date:*

*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 [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).*

### Sponsor Discussion Questions

1. We gather that you had [Number and Type of Interactions]. Tell me more about those interactions.
  - a. Tell me more about what your organization did to prepare for these interactions.
  - b. We saw that you used [Interaction Type] the most frequently. Why was this the case?
  - c. (if applicable) How did FDA's facilitation with external stakeholders impact your experience with these stakeholders?
  - d. Please describe how you collaborated among stakeholders in these interactions.
  - e. Tell me more about the outcomes of these interactions. How did these interactions impact your organization's strategic decision-making process?
  - f. What could FDA do differently to make interactions more valuable?
  - g. What would you do differently to make those interactions with stakeholders more valuable?

- h. What could the stakeholders do differently to make those interactions more valuable?
- 2. I would like to now discuss the outcomes of TAP on your organization. How did your participation in the Pilot affect your device development plan?
  - a. Tell me more about the outcomes associated with interactions with FDA? Did these FDA interactions leave you feeling you had clear next steps provided by FDA? Why is that?
  - b. You [agreed/disagreed] in the survey that the TAP Pilot was a value-add. Why is that?
    - i. Which aspects of the Pilot were particularly valuable to your organization? What factors contributed to an interaction being valuable? Can you give an example?
    - ii. Which aspects were less valuable?
  - c. We see in your survey response that you indicated that the TAP Pilot helped you achieve [a better understanding of regulatory requirements/a better understanding of risk management/a better understanding of commercialization/a better understanding of payer reimbursement/a long-term vision for your organization's device/ensuring your device would be adopted by users/affected your stakeholder engagement plan]. What new information did participation in the TAP Pilot provide you that affected this achievement? How did this play out?
- 3. We understand that you received a breakthrough designation in [Fiscal Year] and you enrolled in the TAP Pilot in [Fiscal Year]. Tell me more about your process entering the Pilot.
  - a. As you enrolled in the Pilot, how helpful did you find the orientation and materials?
  - b. Overall, how prepared did you feel entering the Pilot? What would have made you feel more prepared?
  - c. 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?
  - d. Did you feel you had appropriate resources (time, money, etc.) to fully engage in the Pilot?
  - e. If you had the ability to engage more frequently, would you have? Why or why not?
- 4. We see in your survey response that you provided a Net Promoter Score of [1-10]. Why is that?
- 5. If you had a magic wand, and could change anything about the TAP Pilot, what would you change? Why?
- 6. Those are all the questions I have for you. What else would be valuable for FDA to know about the TAP Pilot?