FDA CDRH TAP Pilot Customer Satisfaction (CSAT) Survey: External Stakeholder

Introduction

FDA contracted with the management consulting firm Eagle Hill Consulting to conduct this survey as an assessment of the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot.

Please provide your feedback by answering the following questions. All responses will be kept confidential. Completing this survey should take approximately 20 minutes.

Your participation / non-participation 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.

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 20 minutes per response, including the time to review instructions and completing the survey. 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.

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Demographics

* 1. Please select your organization type below.

- ◯ Professional Society
- ◯ Patient Organization
- ◯ Payer Subject-matter Expert (SME)
- ◯ Other (please specify)

* 2. What type of role do you hold within your organization?

- ◯ Member
- ◯ Executive
- ◯ Scientific/Technical
- ◯ Advocacy
- ◯ Education
- ◯ Regulatory
- ◯ Clinical
- ◯ Quality
- ◯ Operations
- ◯ Coding/Payment/Coverage
- ◯ Other (please specify)

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Participation in Interactions

* 3. A **TAP interaction** is a strategic engagement, meeting, or communication facilitated by FDA with one or more organizations. **Sponsors** are medical device companies that have been accepted to participate in the TAP Pilot.

Did you or your organization engage in any **TAP interactions with sponsors** through the TAP Pilot?

- ◯ Yes
- ◯ No

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Satisfaction with Interactions

* 4. How satisfied or dissatisfied was your organization with each of the following aspects of FDA-facilitated interactions with **sponsors** through the TAP Pilot?

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
Quality	◯	◯	◯	◯	◯
Frequency	◯	◯	◯	◯	◯
Efficiency	◯	◯	◯	◯	◯
Timeliness	◯	◯	◯	◯	◯

* 5. Were interactions too frequent, too seldom, or just about right?

- ◯ Too frequent
- ◯ Too seldom
- ◯ Just about right

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General TAP Participation

* 6. How much do you agree or disagree with the following statement: TAP interactions with sponsors were **highly collaborative**.

- ◯ Strongly agree
- ◯ Agree
- ◯ Neither agree nor disagree
- ◯ Disagree
- ◯ Strongly disagree

* 7. How much do you agree or disagree that participating in TAP is a **value-add** for your organization?

- ◯ Strongly agree
- ◯ Agree
- ◯ Neither agree nor disagree
- ◯ Disagree
- ◯ Strongly disagree

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General TAP Participation

* 8. In which of the following ways do you or your organization benefit from participation in the TAP Pilot? Please select all that apply.

- [ ] Increased opportunities to build relationships with sponsors.
- [ ] Increased opportunities to build relationships with FDA.
- [ ] Improved understanding of the pre-market medical device review process.
- [ ] Increased awareness of emerging technologies in medicine.
- [ ] Increased awareness of how my stakeholder input can impact/influence the device development process.
- [ ] Greater influence in the device development process.
- [ ] Other (please specify)

- [ ] None of the above

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General TAP Participation

9. Approximately how many employees at your organization are currently involved in participating in the TAP Pilot?

Enter answer as a whole number.

10. Approximately how much total time (in hours) on average does a given employee spend participating in the TAP Pilot in a typical week?

- ◯ 0-8 hours
- ◯ 9-16 hours
- ◯ 17-24 hours
- ◯ 25-32 hours
- ◯ 33-40 hours
- ◯ 41 hours or more

11. How helpful or unhelpful were each of the following in improving your organization's understanding of how to get the most value from the TAP Pilot.

	Very helpful	Helpful	Neither helpful nor unhelpful	Somewhat unhelpful	Very unhelpful	N/A
Materials provided by FDA	◯	◯	◯	◯	◯	◯
Email exchanges between your organization and FDA	◯	◯	◯	◯	◯	◯
TAP webpage on fda.gov	◯	◯	◯	◯	◯	◯
Meetings and phone calls with FDA staff	◯	◯	◯	◯	◯	◯

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Concluding Remarks

12. What suggestions do you have for how FDA could make TAP interactions more valuable?

13. Please provide any other comments or feedback for FDA.

14. If you are willing to participate in a follow-up interview about the TAP Pilot, please provide your name and email address below.

Name	
Company	
Email Address	
Phone Number	

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Rationale for No Interactions

15. Please describe why you have NOT had any interactions in the TAP Pilot thus far.

- [ ] Recently joined the TAP Pilot.
- [ ] Not prepared for interactions.
- [ ] Scheduling difficulties.
- [ ] Sponsor failed to follow up to have interaction.
- [ ] Other organizational priorities.
- [ ] Interaction request not received.
- [ ] Other (please specify)