

FDA CDRH TAP Pilot Customer Satisfaction (CSAT) Survey: Sponsor

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 PRASStaff@fda.hhs.gov.

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Sponsor Demographics

* 1. What position or role do you hold within your organization?

- Executive
- Engineering
- Operations
- Regulatory
- Clinical
- Quality
- Manufacturing
- Other (please specify)

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Sponsor Demographics

* 2. What size is your organization?

- 10 employees or less
- 11 to 50 employees
- 51 to 100 employees
- 101 to 250 employees
- 251 to 500 employees
- 501 to 1000 employees
- 1001 to 5000 employees
- 5001 employees or more

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Sponsor Demographics

* 3. How long has your organization been operating in the medical device space?

- Less than 2 years
- 2 years to less than 5 years
- 5 years to less than 10 years
- 10 years to less than 20 years
- 20 years or more

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Sponsor Demographics

* 4. A TAP interaction is a strategic engagement, meeting, or communication with one or more organizations. TAP interactions include:

- **Formal teleconferences with FDA:** A teleconference that requires formal amendment submission.
- **Informal check-ins with FDA:** A routine or ad-hoc touch-base that is not documented as a TAP amendment.
- **Written feedback:** A requested TAP amendment on biocompatibility, sterility, and other topics from FDA.
- **Voluntary Interactions with non-FDA stakeholders, facilitated by FDA** (e.g., payer consultants/subject matter experts (SMEs), healthcare providers, patient organizations/SMEs).

How many total interactions has your organization had while participating in the TAP Pilot?

- 0 interactions
- 1 to 5 interactions
- 6 to 10 interactions
- 11 to 20 interactions
- 21 interactions or more

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Sponsor Demographics

* 5. An **amendment** is a requested and documented interaction with FDA or non-FDA stakeholders. How many total amendments has your organization requested with the TAP Pilot?

- 0 amendments
- 1 to 3 amendments
- 4 to 6 amendments
- 7 to 9 amendments
- 10 amendments or more

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Interaction Type: Formal Teleconferences with FDA

* 6. Did your organization engage in **formal teleconferences with FDA** (teleconferences that require formal amendment submission) during the TAP Pilot period?

Yes

No

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Satisfaction with Formal Teleconferences with FDA

Formal teleconferences with FDA are those that require formal amendment submission.

* 7. How satisfied or dissatisfied was your organization with each the following aspects of **formal teleconferences with FDA**?

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
Quality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frequency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Efficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 8. Were your **formal teleconferences with FDA** too frequent, too seldom, or just about right?

- Too frequent
- Too seldom
- Just about right

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Interaction Type: Informal Check-ins with FDA

* 9. Did your organization engage in **informal check-ins with FDA** (routine or ad-hoc touch-bases that is not documented as a TAP amendment) during the TAP Pilot period?

Yes

No

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Satisfaction with Informal Check-ins with FDA

Informal Check-ins with FDA are routine or ad-hoc touch-bases that are not documented as a TAP amendment.

* 10. How satisfied or dissatisfied was your organization with each the following aspects of **informal check-ins with FDA**?

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
Quality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frequency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Efficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 11. Were your **informal check-ins with FDA** too frequent, too seldom, or just about right?

- Too frequent
- Too seldom
- Just about right

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Interaction Type: Written Feedback from FDA on Biocompatibility and Sterility Topics

* 12. Did your organization engage in **written feedback from FDA on biocompatibility and sterility topics** during the TAP Pilot period?

Yes

No

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Satisfaction with Written Feedback from FDA on Biocompatibility and Sterility Topics

Written Feedback from FDA on Biocompatibility and Sterility Topics are those requests that requires an amendment submission.

* 13. How satisfied or dissatisfied was your organization with each the following aspects of **written feedback from FDA on biocompatibility and sterility topics**?

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
Quality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frequency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Efficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 14. Was your **written feedback from FDA on biocompatibility and sterility topics** too frequent, too seldom, or just about right?

- Too frequent
- Too seldom
- Just about right

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Interaction Type: Written Feedback from FDA on Other Non-Biocompatibility and Sterility Topics

* 15. Did your organization engage in **written feedback from FDA on other NON-biocompatibility and sterility topics** during the TAP Pilot period?

Yes

No

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Satisfaction with Written Feedback from FDA on Other Non-Biocompatibility and Sterility Topics

Written Feedback from FDA on Other Non-Biocompatibility and Sterility Topics are those requests that requires an amendment submission.

* 16. How satisfied or dissatisfied was your organization with each of the following aspects of **written feedback from FDA on other NON-biocompatibility and sterility topics?**

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
Quality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frequency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Efficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 17. Was your **written feedback from FDA on other NON-biocompatibility and sterility topics** too frequent, too seldom, or just about right?

- Too frequent
- Too seldom
- Just about right

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Voluntary Interactions With Non-FDA Stakeholders During TAP Pilot

* 18. Did your organization engage in **voluntary interactions with non-FDA stakeholders facilitated by FDA** during the TAP Pilot (e.g., payer consultants/subject matter experts (SMEs), healthcare providers, patient organizations/SMEs)?

By non-FDA, we are referring to external individuals or groups that are not contracted or employed by the FDA.

Yes

No

Voluntary Interactions During TAP Pilot: Payer Consultants/SMEs

19. Did your organization engage in voluntary interactions with **non-FDA payer consultants/subject matter experts (SMEs)** facilitated by FDA?

Payer consultants/subject matter experts (SMEs): Individuals that advise on payment for services rendered by a healthcare provider.

Yes

No

Primary Drivers for Non-Interactions: Payer Consultants/SMEs

* 20. What is the *primary* reason for NOT interacting with **non-FDA payer consultants/subject matter experts (SMEs)** through the TAP Pilot?

- It is not our highest priority right now
- Timing is not right
- We do not have the bandwidth
- Not sure how to initiate
- Do not see the value
- We have our own experts/contacts
- Other (please specify)

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Satisfaction of Interactions with Non-FDA Payer Consultants/Subject Matter Experts (SMEs)

Payer consultants/SMEs are individuals that advise on payment for services rendered by a healthcare provider.

* 21. How satisfied or dissatisfied was your organization with each the following aspects of voluntary interactions with **non-FDA payer consultants/subject matter experts (SMEs)** facilitated by FDA?

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
Quality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frequency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Efficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 22. Were your voluntary interactions with **non-FDA payer consultants/subject matter experts (SMEs)** facilitated by FDA too frequent, too seldom, or just about right?

- Too frequent
- Too seldom
- Just about right

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Voluntary Interactions During TAP Pilot: Healthcare Providers and Professional Societies

* 23. Did your organization engage in voluntary interactions with **non-FDA healthcare providers and professional societies** facilitated by FDA?

Healthcare Providers and Professional Societies: Individuals or groups that provide feedback on clinical evidence generation, reimbursement, and clinical practice/new technology adoption.

Yes

No

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Primary Drivers for Non-Interactions: Healthcare Providers and Professional Societies

* 24. What is the *primary* reason for NOT interacting with **non-FDA healthcare providers and professional societies** through the TAP Pilot?

- It is not our highest priority right now
- Timing is not right
- We do not have the bandwidth
- Not sure how to initiate
- Do not see the value
- We have our own experts/contacts
- Other (please specify)

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Satisfaction of Interactions with Non-FDA Healthcare Providers and Professional Societies

Healthcare Providers and Professional Societies are individuals or groups that provide feedback on clinical evidence generation, reimbursement, and clinical practice/new technology adoption.

* 25. How satisfied or dissatisfied was your organization with each the following aspects of voluntary interactions with **non-FDA healthcare providers and professional societies** facilitated by FDA?

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
Quality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frequency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Efficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 26. Were your voluntary interactions with **non-FDA healthcare providers and professional societies** facilitated by FDA too frequent, too seldom, or just about right?

- Too frequent
- Too seldom
- Just about right

Voluntary Interactions During TAP Pilot: Patient Organizations/SMEs

* 27. Did your organization engage in voluntary interactions with **non-FDA patient organizations/subject matter experts (SMEs)** facilitated by FDA?

Patient Organizations/SMEs: Individuals or groups that promote the needs of patients by providing education and training, support, research, clinical trial recruitment, and medical information.

Yes

No

Primary Drivers for Non-Interactions: Patient Groups/SMEs

* 28. What is the *primary* reason for NOT interacting with **non-FDA patient organizations/subject matter experts (SMEs)** through the TAP Pilot?

- It is not our highest priority right now
- Timing is not right
- We do not have the bandwidth
- Not sure how to initiate
- Do not see the value
- We have our own experts/contacts
- Other (please specify)

FDA CDRH TAP Pilot Customer Satisfaction (CSAT) Survey: Sponsor

Satisfaction with Interactions with Non-FDA Patient Organizations/Subject Matter Experts (SMEs)

Patient Organizations/SMEs are individuals or groups that promote the needs of patients by providing education and training, support, research, clinical trial recruitment, and medical information.

* 29. How satisfied or dissatisfied was your organization with each the following aspects of voluntary interactions with **non-FDA patient organizations/subject matter experts (SMEs)** facilitated by FDA?

	Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
Quality	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Frequency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Efficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Timeliness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 30. Were your voluntary interactions with **non-FDA patient organizations/subject matter experts (SMEs)** facilitated by FDA too frequent, too seldom, or just about right?

- Too frequent
- Too seldom
- Just about right

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Voluntary Interactions Outside TAP Pilot

* 31. Does your organization have experience interacting with external stakeholders (e.g., payer consultants/SMEs, healthcare providers, patient organizations/SMEs) **outside of the TAP Pilot** (that is, without FDA involvement)?

Yes

No

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Voluntary Interactions: Compare In/Outside TAP Pilot

* 32. Were interactions with external stakeholders facilitated by FDA through the TAP Pilot better or worse than other external stakeholder interactions NOT facilitated by FDA?

- Much better
- Somewhat better
- About the same
- Somewhat worse
- Much worse

33. Please explain what made interactions facilitated by FDA better or worse.

34. What is the MOST significant action that you took as a result of what you learned through interactions with non-FDA stakeholders?

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Topics of Interactions

* 35. Across all interaction types, which of the following topics did you cover in your interactions? Please select all that apply.

- Regulatory Requirements
- Biocompatibility and Sterility Topics
- Design/User Needs
- Commercialization Plan
- Device Development Plan
- Coding, Payment, and Coverage Requirements
- Patient Engagement Topics
- Clinical Evidence Generation
- Regulatory Evidence
- Payer Evidence
- Other (please specify)

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Overall Satisfaction

* 37. Overall, how satisfied or dissatisfied is your organization with its participation in the TAP Pilot?

- Very satisfied
- Satisfied
- Neither satisfied nor dissatisfied
- Dissatisfied
- Very dissatisfied

38. What were the primary drivers that influenced your response to the previous question?

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Overall Satisfaction

39. Which TAP Pilot interaction type do you prefer most?

- Formal Teleconference
- Written feedback
- External stakeholder engagement
- Informal check-in/touch-base
- No preference

* 40. How likely are you to recommend TAP to another medical device company like yours?
Please indicate on a scale of 0 (not at all likely) to 10 (extremely likely).

A horizontal scale from 0 to 10. The number 0 is on the left, 5 is in the middle, and 10 is on the right. A circular slider knob is positioned at 0. A grey bar extends from the knob to the right. At the far right end, there is a small square text input box.

Outcomes and Impacts of the TAP Pilot: Strategic Decision-Making

* 42. To what extent have TAP Pilot interactions had a positive or negative effect on your organization's strategic decision-making (for example, regarding development or commercialization of a device)?

- Major positive effect
- Minor positive effect
- No effect
- Minor negative effect
- Major negative effect

Outcomes and Impacts of the TAP Pilot: Strategic Decision-Making

Regulatory Strategy

* 43. Has your organization realized **benefits to your regulatory strategy** as a result of your participation in the TAP Pilot?

Yes

No

Outcomes and Impacts of the TAP Pilot: Strategic Decision-Making

Regulatory Strategy

* 44. Which of the following **benefits to your regulatory strategy** has your organization realized as a result of your participation in the TAP Pilot? Please select all that apply.

- Aligned with FDA on overall regulatory strategy for our device.
- Increased timely premarket interactions with FDA.
- Received clarity and actionable options on the next steps for our device from FDA.
- Aligned with FDA on specific steps leading to market authorization for our device.
- Obtained clarity on evidence collection to support market approval.
- Identified and mitigated regulatory risks.
- Consider our market differentiation.
- Improve our device development strategy.
- Other (please specify)

Outcomes and Impacts of the TAP Pilot: Strategic Decision-Making

Commercialization and Patient Access Strategy

* 45. Has your organization realized **benefits to your commercialization and patient access strategy** as a result of your participation in the TAP Pilot?

Yes

No

Outcomes and Impacts of the TAP Pilot: Strategic Decision-Making

Commercialization and Patient Access Strategy

* 46. Which of the following **benefits to your commercialization and patient access strategy** has your organization realized as a result of your participation in the TAP Pilot? Please select all that apply.

- Better understood the full path to market adoption for our device.
- Accessed various external stakeholders (e.g., payer consultants/SMEs, healthcare providers, patient organizations/SMEs).
- Better understood our device's value proposition and the ways we can demonstrate its value.
- Became better informed about the reimbursement landscape (e.g., coding, coverage, and payment).
- Identified reimbursement risks for our device and set a clear path to mitigating those risks.
- Other (please specify)

Outcomes and Impacts of the TAP Pilot: Marketing Application

The following questions ask about outcomes and impacts achieved from participating in the TAP Pilot as they relate to marketing applications.

* 47. **Evidence generation** is the use of adequate and well-controlled investigations conducted by experts, including clinical studies, to evaluate the effectiveness and safety of the treatment in question.

How much do you agree or disagree that your organization has a **better understanding** of FDA's expectations regarding evidence generation for the purpose of marketing authorization as a result of participating in the TAP Pilot?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- N/A - We did not discuss this topic through the TAP Pilot

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Outcomes and Impacts of the TAP Pilot: Marketing Application

The following questions ask about outcomes and impacts achieved from participating in the TAP Pilot as they relate to marketing applications.

* 48. Does your organization expect to bring your device to market?

- Yes
- No
- Not Decided

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Outcomes and Impacts of the TAP Pilot: Marketing Application

* 49. How confident is your organization in gaining market approval of your device from FDA on its **first attempt** (i.e., you will NOT be asked for additional information in response to your initial market submission for your device for the proposed indications for use)?

- Extremely confident
- Very confident
- Somewhat confident
- Slightly confident
- Not at all confident

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General Information

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

Enter answer as a whole number.

53. 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

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Concluding Remarks

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

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

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

Name	<input type="text"/>
Company	<input type="text"/>
Email Address	<input type="text"/>
Phone Number	<input type="text"/>

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Rationale for No Interactions

57. Why has your organization NOT had any interactions in the TAP Pilot thus far? Please select all that apply.

- Recently joined the TAP Pilot.
- Not prepared for interactions/written feedback.
- Scheduling difficulties.
- Other organizational priorities.
- TAP didn't seem like it would provide value to our organization.
- Other (please specify)