

PRA External Data Collection Methods Companion Document

Purpose: This document serves as a repository for companion materials essential for external data collection methods, encompassing resources such as email scripts and Microsoft Teams meeting invitations.

CSAT Survey Email Script

To: TAP Participants (Sponsors) / External Stakeholders

From: TAP Assessment Team

Subject: Action Required: Please Take Our TAP Pilot Participation Survey

Hello,

You have been selected to participate in this satisfaction survey due to your participation in the TAP Pilot. Please provide your feedback by answering the following questions. Your response is voluntary, and all responses will be kept confidential. Completing this survey should take approximately 20 minutes. Please note, the survey link will close on [Date].

[Unique CSAT Survey Link]

Kind regards,

Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices and Radiological Health

The FDA contracted with the management consulting firm Eagle Hill Consulting to conduct this survey in support of MDUFA V performance goals and procedures, specifically to conduct an assessment of the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot using a participant survey and quantitative and qualitative success metrics.

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.

CSAT Survey Email Script (Reminder 1)

To: TAP Participants (Sponsors) / External Stakeholders

From: TAP Assessment Team

Subject: REMINDER: Don't forget to take the TAP Pilot Participation Survey

Hello,

On [Date], we sent an email requesting your feedback. Your opinion is very important to us, so please consider taking a few minutes to provide your feedback in the following survey.

[Unique CSAT Survey Link]

Your response is voluntary, and all responses will be kept confidential. Completing this survey should take approximately 20 minutes. Please note, the survey link will close on [Date].

Kind regards,

Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices and Radiological Health

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CSAT Survey Email Script (Reminder 2)

To: TAP Participants (Sponsors) / External Stakeholders

From: TAP Assessment Team

Subject: LAST CALL: TAP Pilot Participation Survey

Hello,

This is your final chance to provide your feedback on your participation in the TAP Pilot. Your opinion is very important to us, so please consider taking a few minutes to provide your feedback in the following survey.

Your response is voluntary, and all responses will be kept confidential. Completing this survey should take approximately 20 minutes. Please note, the survey link will close on **[Date]**.

[Unique CSAT Survey Link]

Kind regards,

Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices and Radiological Health

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Sponsor Interview Meeting Invitation

To: TAP Participant (Sponsor)

From: EHC

Subject: TAP Pilot Participation Interview

Hello **[Name]**,

Thank you for volunteering to participate in an interview with the Eagle Hill team regarding your involvement in the TAP Pilot. We look forward to learning more about your experience. Please let me know if the time scheduled works for you. Kindly note that no preparation is required.

However, you will be provided with a list of discussion questions a few days prior to the interview.

Thank you in advance for your time, please do not hesitate to reach out if you have any questions.

Kind regards,

Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices and Radiological Health

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External Stakeholder Meeting Invitation

To: External Stakeholder

From: EHC

Subject: TAP Pilot Participation Interview

Hello **[Name]**,

Thank you for volunteering to participate in an interview with the Eagle Hill team regarding your involvement in the TAP Pilot. We look forward to learning more about your experience. Please let me know if the time scheduled works for you. Kindly note that no preparation is required.

However, you will be provided with a list of discussion questions a few days prior to the interview.

Thank you in advance for your time, please do not hesitate to reach out if you have any questions.

Kind regards,

Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices and Radiological Health

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Solicitation for Interview: Sponsors and External Stakeholders

To: TAP Participant (Sponsor) / External Stakeholder

From: EHC

Subject: You've Been Selected: TAP Pilot Participation Interview

Hello [Name],

You have been selected to participate in an interview regarding your experience and participation in the TAP Pilot. While this interview is voluntary, your opinion is very important to us. We are eager to learn more about your experience in the TAP Pilot.

Please let me know if the time scheduled works. Kindly note that no preparation is required.

However, you will be provided with a list of discussion questions a few days prior to the interview. Thank you in advance for your time, and please let me know if you have any questions.

Kind regards,

Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices and Radiological Health

The FDA contracted with the management consulting firm Eagle Hill Consulting to conduct this survey in support of MDUFA V performance goals and procedures, specifically to conduct an assessment of the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot using a participant survey and quantitative and qualitative success metrics.

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Interview Discussion Questions

To: TAP Participant (Sponsor) / External Stakeholders

From: EHC

Subject: You've Been Selected: TAP Pilot Participation Interview

Hello [Name],

Please see below for a complete list of discussion questions for this meeting. Thank you in advance for your time, and please let me know if you have any questions.

[List of questions will be tailored to different participants]

Kind regards,

Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices and Radiological Health

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Pulse Survey Email Script

To: TAP Participants (Sponsors)/ External Stakeholders

From: TAP Assessment Team

Subject: Action Required: TAP Pilot Participation Pulse Survey

Hello,

Thank you for participating in a TAP Pilot interaction. Please take this 2-question survey to provide feedback about your experience. Your response is voluntary, and all responses will be kept confidential. Completing this survey should take approximately 2 minutes.

[\[Pulse Survey Link\]](#)

Kind regards,

Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices and Radiological Health

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Observational Meeting Email Script

To: TAP Participants (Sponsors)/ External Stakeholders

From: EHC

Subject: You've Been Selected: Meeting to be Observed

Hello,

I hope this email finds you well. As a part of the MDUFA V performance goals and procedures, the FDA has contracted with the management consulting firm Eagle Hill Consulting to conduct a comprehensive assessment of the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot.

A key component of the data collection methodology in this assessment is observations of interactions, as teleconferences are an integral part of the TAP Pilot. Eagle Hill Consulting is kindly requesting to observe the upcoming meeting on [\[Date\]](#) at [\[Time\]](#) with [\[Participant\]](#).

Meeting observations are voluntary. Please respond to this message if you would **not** like your meeting to be observed. All information gathered from the meeting will remain anonymized and confidential.

Kind regards,
Eagle Hill Consulting, LLC on behalf of the Food and Drug Administration, Center for Devices
and Radiological Health

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