United States Food and Drug Administration

TOTAL PRODUCT LIFE CYCLE ADVISORY PROGRAM PILOT

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

1. Respondent Universe and Sampling Methods

As described in the Supporting Statement Part A (SSA), the MDUFA V commitment letter states the FDA will conduct an assessment of the overall outcomes of the Total Product Life Cycle Advisory Program (TAP) Pilot that will include a participant satisfaction survey and quantitative and qualitative success metrics that include, but are not limited to: (a) the extent to which FDA is successful at meeting the quantitative goals described in V.J.3.b of the MDUFA V commitment letter; (b) participant satisfaction with the timeliness, frequency, quality, and efficiency of interactions with and written feedback from FDA; (c) participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized); and (d) an overall assessment of the outcomes of the Pilot and opportunities for improvement.

In addition to the application to participate in the TAP Pilot, the information collections associated with the TAP Pilot include the participant satisfaction survey, participant pulse surveys, interviews, and observations with TAP Pilot participants.

Manufacturers of devices reviewed by a participating FDA Center for Devices and Radiological Health (CDRH) Office of Health and Technology (OHT) may be enrolled in the voluntary TAP Pilot using the following enrollment criteria:

- Devices will be those with a granted Breakthrough Device designation;*
- Potential participants will not have submitted a Pre-Submission about the device after being granted a Breakthrough Device designation;
- Devices will be early in their device development process (e.g., have not yet initiated a pivotal study for the device) at time of enrollment; and
- Each potential participant will have a maximum of one device enrolled in the TAP Pilot per fiscal year.

*In FY2026-27, devices with a granted request for inclusion in the Safer Technologies Program (STeP) may also be eligible.

The respondent universe for the TAP Pilot Participant Satisfaction Survey (CSAT) survey consists of all TAP Pilot participants. Given the voluntary nature of participation in both the TAP Pilot and each data collection type, we expect response rates to meet or exceed the levels required for obtaining statistically viable results (i.e., generally meeting or exceeding 80%).

Table 1 below outlines our projected sampling plan, detailing the anticipated universe size, proposed sampling method, expected sample size, and the reasoning behind our sampling

choices for each information collection type. Additional detail regarding these sampling methodologies will be detailed in Section 2 below.

Table 1 — Estimated Sampling

Information Collection Type	Expected Universe Size	Proposed Sampling Method	Expected Sample Size	Rationale
Application to Participate in TAP Pilot Program	225	Entire Universe	225	FDA estimates that 100% of the respondents will use electronic means (via the portal) to request approval to participate in the TAP Pilot.
TAP Pilot Participant Satisfaction Survey (CSAT Survey)	234[a]	Entire Universe	234	All sponsors and external stakeholders who participate in the TAP Pilot will be invited to take the survey.
TAP Pilot Participant Interviews	234[b]	Convenience Stratified Sampling	60	Interviews will provide supplemental information to CSAT survey responses. Sampling will be based on convenience, availability, respondent preference, and FDA resource limitations.
TAP Pilot Passive Observations	1,114[c]	Convenience Stratified Sampling	100	Meeting observations will allow us to gather unbiased qualitative data from TAP Pilot meetings and teleconferences. Sampling will be based on convenience, availability, respondent preference, and FDA resource limitations.
TAP Pilot Participant Pulse Surveys	277[d]	Stratified Systematic Sampling Approach	105	Pulse surveys will allow us to receive general feedback and real-time data regarding interaction satisfaction. We plan to send pulse surveys after every 3 interactions by type of interaction (e.g., teleconference, written feedback) and the OHT to which the sponsor's device is aligned.

2. Procedures for the Collection of Information

In addition to the application to participate in the TAP Pilot, we will use four information collection methods. The procedures for each collection method are delineated below.

Application to Participate in TAP Pilot Program

[a] We expect up to 200 TAP device manufacturers based on total potential TAP enrollment by FY26.
[b] Includes all TAP device manufacturers, plus external stakeholder groups involved in the Pilot (est. 34 entities)
[c] Meeting observations universe estimated based on an average of ~4 meetings/teleconferences per sponsor.
[d] Pulse surveys universe estimated based on linear function of the running total of sponsors in TAP and formal amendment requests expressed as an equation, $y = 1.364x + 4.2612$, with $x = 200$.

We will develop a software portal mechanism through which sponsors interested in device enrollment into the TAP Pilot program can submit an application to join online. We estimate that 100% of the respondents will use electronic means via the portal to request approval to participate in the TAP Pilot. Our sample size estimate of 225 was calculated based on the TAP Pilot Enrollment and Expansion Schedule, which includes the scope and projected participation in the TAP Pilot within the next user fee cycle, referenced in the MDUFA V commitment letter (MDUFA V.J.3).

TAP Pilot Participant Satisfaction Survey (CSAT Survey)

We will survey all TAP Pilot participants, including sponsors and external stakeholders who have participated in the Pilot since October 1, 2023. Our sample size estimate of 234 was calculated using the estimated total number of sponsors combined with the estimated total number of external stakeholders participating in the TAP Pilot.

We will deliver web-based CSAT surveys by email directly to respondents. Each email will contain a hot link to the CSAT survey, housed in SurveyMonkey. This method has been selected because it incurs a minimal expense. The CSAT survey will remain open for 3 weeks, and we will send at least two follow-up emails, if needed, to remind respondents to participate. Given the voluntary nature of participation in both the TAP Pilot and the CSAT survey, we anticipate a high level of engagement from participants owing to their inherent investment in the TAP Pilot. The primary purpose of the CSAT surveys is to capture the satisfaction of sponsors and external stakeholders regarding their interactions within the TAP Pilot. We do not plan on using any estimation procedures for the generalization of results from the survey, since we will be collecting data from the entire population of interest.

TAP Pilot Participant Interviews

We will implement a stratified convenience sampling method for interviews. The stratification of sponsors will consider the FDA OHT to which the sponsor's device is assigned (e.g., OHT2 Cardiovascular Devices, OHT5 Neurological & Physical Medicine Devices, etc.), organization size (e.g., Large MedTech company vs. small VC-backed startup), and engagement level in the TAP Pilot. External stakeholders will be stratified based on their type, such as professional society, patient organization, or payer subject-matter expert (SME). Our sample size estimate of 60 was determined based on strata including OHT, organization size, engagement level, and types of external stakeholders. The plan is to conduct interviews with two entities from each unique combination of those factors.

We do not anticipate using estimation procedures for interviews. The data collected will primarily be qualitative in nature, and our main goals with the interviews are to clarify survey responses and identify improvement opportunities.

We will primarily solicit interview participation by asking TAP Pilot participants to voluntarily opt in by providing their name and email address through the CSAT survey. Additionally, we will employ a secondary method of solicitation through direct outreach to TAP Pilot participants via email to obtain their involvement in interviews. We will conduct interviews virtually via

Microsoft Teams or an equivalent platform and send interview invitations with Teams meeting links via email in advance. Virtual interviews will increase likely response rates and reduce burden on the participants and the FDA in terms of time and cost.

TAP Pilot Passive Observations

We will implement a stratified convenience sampling method for formal and informal teleconferences based on the FDA OHT to which the sponsor's device is assigned (e.g., OHT2 Cardiovascular Devices, OHT5 Neurological & Physical Medicine Devices, etc.), organization size (e.g., Large MedTech company vs. small VC-backed startup), and engagement level in the TAP Pilot. We do not anticipate needing estimation procedures for passive observations, as the data collected will primarily be qualitative in nature. Our sample size estimate of 100 was calculated based on strata including OHT, organization size, engagement level, and type of teleconference. The plan is to observe two meetings from each unique combination of strata.

FDA Staff or contractors will attend and passively observe formal and informal teleconferences in the TAP Pilot and subsequently complete standardized observation forms to collect data. TAP Pilot participants will receive emails in advance notifying them of the intention to observe their meeting. Participants will have the ability to opt-out of observation if desired. The primary purpose of observing meetings is to help us gather unbiased qualitative data about in-person interactions in the TAP Pilot to supplement data gathered via other methods.

TAP Pilot Participant Pulse Surveys

We will use a systematic sampling method for pulse surveys, sending 1 after every 3 interactions by type of interaction (e.g., teleconference, written feedback) and OHT. Our sample size estimate of 105 was calculated based on historical TAP Pilot data. Using this systematic method, 38% of interactions would have been surveyed based on TAP Pilot interactions to date. Assuming this proportion holds for the estimated total universe of interactions in the TAP Pilot (approx. 277), we are left with 105 for our sample size. We believe this sampling method allows for sufficient accuracy in estimating satisfaction with interactions while also reducing burden on respondents and FDA.

We will send pulse surveys to TAP Pilot participants via email within 3 business days of completed formal interactions in the TAP Pilot. Formal interactions refer to documented amendments within the CDRH IT system, including requests for formal teleconferences and written feedback from FDA. These do not include informal check-ins or other ad hoc meetings in the TAP Pilot. The pulse survey link will remain open for 10 business days to allow time for respondents to complete the survey. The primary purpose of pulse surveys is to gather real-time data regarding interaction satisfaction to supplement information gathered via the CSAT survey.

3. Methods to Maximize Response Rates and Deal with Non-Response

All data collection instruments listed above, and the questions asked therein, have undergone an FDA social scientist review to reduce potential biases and increase the validity and accuracy of responses. All scripts and templates for email outreach, meeting invitations, and other messaging

also went through review. These scripts and templates may be found in a separate attachment to this information collection request.

In addition, we plan to employ a variety of strategies to elevate response rates and minimize respondent burden to all data collection requests, including:

- The team will notify TAP participants in advance of when the survey will be sent to increase general awareness.
- The team will send the survey via email and use a web-based survey tool to minimize burden and expense.
- The team will provide ample time for the respondents to complete surveys by keeping surveys open for extended periods, thereby accounting for the schedules of respondents and making the survey available to respondents during weeks and times that do not overlap with major activities or potential scheduling conflicts.
- The team will also maintain a dataset containing a list of respondents, respondent POC's, and email addresses to efficiently track survey response rates. Regularly scheduled and targeted email reminders will be sent during the data collection period to encourage participation. Verbal notifications and messaging in existing meetings with TAP participants will also be conducted by FDA staff to encourage survey participation.
- In our email scripts and communications, we emphasize the importance of each respondent's participation and explain how the information collection informs the MDUFA-required TAP Assessment as well as improvement opportunities for the TAP program overall. We will also assure participants that we will keep their responses private in each data collection instrument.
- We also plan to send a thank you message and communicate the summarized survey responses to participating sponsors via email.

We do not anticipate non-response bias to be an issue for this data collection. We assume that sponsors who choose not to participate in the CSAT survey or any of the other information collection requests included in this package are very likely to not be active participants in the TAP Pilot, as both are voluntary. Because our goal for these information collections is to gather data related to satisfaction, outcomes, and improvement opportunities relative to the TAP Pilot, we anticipate there to be a very low risk of missing information about the TAP Pilot program from entities who do not, or have not, actively engaged in the TAP Pilot and did not take surveys. Thus, we expect overall non-response bias to be negligible and should not hinder us from achieving our goals with this data collection.

4. Test of Procedures or Methods to be Undertaken

Several rounds of pre-testing occurred to improve the accuracy and reliability of all data collection instruments mentioned above. Pre-testing included a review by contractors and FDA staff familiar with the TAP Pilot of instrument question phrasing, logic, layout, and estimated burden. All survey and interview questions have also been reviewed for plain language. An FDA social scientist, independent of the TAP Pilot, also completed a thorough review of all the data collection instruments, including reviewing instruments for potential sources of bias, consistency, and accessibility. Additional testing of survey logic, format, and flow within the

SurveyMonkey platform was completed to improve readability. clarity, and the user experience. This final testing was also done with contractors and FDA staff familiar with the TAP Pilot . No respondents or end users were consulted for testing of these data collection instruments.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals were involved in the planning and creation of the data collection instruments and the sampling approach for this request. They will also be responsible for collecting and analyzing data for the agency. No statisticians were consulted for this data collection since we are gathering data from the entire respondent universe through the survey and primarily using convenience sampling for other information collection methods.

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