December 2025

Total Product Lifecycle Advisory Program (TAP) Pilot Assessment

Final Assessment Report

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Executive Summary

Purpose and Methodology

The Food and Drug Administration (FDA) commissioned this independent third-party assessment of the Total Product Lifecycle Advisory Program (TAP) Pilot to evaluate its progress in achieving the goals outlined under the Medical Device User Fee Amendments (MDUFA) V. This assessment focused on how effectively the program supports participating device companies (referred to as Innovators) and advances their medical devices toward key regulatory and developmental outcomes.

The assessment, conducted by Eagle Hill Consulting from October 2023 to August 2025, used a robust mixed-methods approach to provide a complete and inclusive evaluation of the TAP Pilot's successes and areas for improvement.

The methodology applied five data collection tools across 95 TAP Innovators and 73 non-FDA parties[1]:

1. **Customer Satisfaction Surveys:** 209 surveys administered via email to Innovators and non-FDA parties across two waves (2024 and 2025), with an overall response rate of 81% for Innovators and 54% for non-FDA parties
2. **Participant Interviews:** 54 interviews conducted with Innovators and non-FDA parties across two waves (2024 and 2025)
3. **Meeting Observations:** 82 meetings observed between Innovators and FDA over an eight-month period
4. **Pulse Surveys:** 96 post-interaction pulse surveys administered via email to Innovators over an eight-month period, with a 35% response rate
5. **Administrative Data Review:** Analyzed FDA database and system data over the assessment period (2023 to 2025)

Most data collection was conducted on an ongoing basis, while customer satisfaction surveys and participant interviews were carried out in two waves (one in 2024 and another in 2025), approximately nine months apart.

At the end of the assessment period, participating Innovators had been enrolled in the TAP Pilot for an average (mean) of 15 months. More than half (52%) joined within the past 12 months, while the remaining 48% had been engaged for longer than a year.

Key Findings

The TAP Pilot demonstrates exceptional performance across all key metrics, indicating strong progress toward achieving its outcomes:

- ✓ **MDUFA V Performance Success**: During the assessment period (October 2023 to August 2025), the program exceeded all quantitative performance goal targets but one. With a total of 195 TAP amendments completed, 98% (91/93) of teleconferences were completed on time, 100% (90/90) of written feedback on other topics met deadlines, and

[1] These numbers reflect the number of Innovators and non-FDA parties engaged in the Pilot throughout data collection. Not all are listed on FDA's website and were surveyed regardless of whether they engaged with a TAP Innovator or not.

83% (10/12) of biocompatibility and sterility feedback was delivered as scheduled[2]. An amendment is a requested and documented interaction with FDA specific to regulatory topics, tracked using an existing CDRH amendment mechanism to align with MDUFA V quantitative performance metrics.
Across FY2024, all targets were met, with 97% (29/30) of teleconferences, 100% (39/39) of written feedback on other topics, and 100% (3/3) of written feedback on biocompatibility and sterility topics completed on time. So far in FY2025 (October 2024 – August 2025), 98% (62/63) of teleconferences, 100% (51/51) of written feedback on other topics, and 78% (7/9) of written feedback on biocompatibility and sterility topics have been completed on time.

- ✓ **Significant Stakeholder Engagement:** 1,240 TAP interactions occurred between FDA and Innovators during the assessment period, including 117 FDA-facilitated interactions with non-FDA parties such as providers, payers, and patient organizations. Among Innovators with prior experience engaging non-FDA parties outside the Pilot, 100% reported that TAP-facilitated interactions were equal to or better than their previous experiences.

- ✓ **Overall Stakeholder Satisfaction:** The program achieved an exceptional Net Promoter Score of 83 by Innovators (increasing from 77 during survey wave 1). 96-98% of innovators were satisfied with FDA interactions and 84-91% with non-FDA party interactions.

- ✓ **Enhanced Evidence Generation Understanding:** 96% of Innovators reported an improved understanding of FDA's evidence generation expectations, a 23-percentage point gain from wave 1 to wave 2 among those who completed both surveys, highlighting the program's improvement over time.

- ✓ **Improved Strategic Decision-Making:** 93% of Innovators reported that TAP interactions positively influenced their strategic decision-making, and 87% highlighted the collaborative framework's role in shaping clinical trial design, hiring, and resource allocation.

- ✓ **Accelerated Development Timelines:** 96% of Innovators expressed confidence in gaining market approval, with 53% citing TAP's value in "de-risking" device development. Additionally, 40% of interviewed Innovators reported tangible time and cost savings (See Figure 9 Case Study: FDA Collaboration Accelerates Device Development).

For additional details demonstrating the performance of the TAP Pilot, please refer to Appendix 1.9 Additional TAP Participant Case Studies.

Summary of Improvement Opportunities

Throughout the data collection, three interconnected improvement areas emerged from stakeholder feedback and operational analysis that aim to transform the TAP Pilot into a robust, scalable framework:

[2] See footnote 2 in **Key Findings** for additional details on the missed biocompatibility and sterility feedback target.

Process Standardization and Documentation: Rapid program expansion may have created some inconsistent internal processes and unclear roles among participants. Recommended solutions include enhancing documentation, defining clear roles and responsibilities, and standardizing internal operations to improve operational efficiency and scalability.

Stakeholder Communication and Education: Communication gaps exist regarding program expectations and stakeholder roles, particularly for non-FDA parties. Improvements should focus on enhanced intake processes, improved educational materials, and clearer guidelines for optimal program utilization.

Program Maturity and Scalability: The TAP Pilot's rapid growth has outpaced its infrastructure, review processes, and external networks. More robust enrollment criteria, stronger operational systems, enhanced program promotion, and expanded stakeholder connections are needed to support scalability and consistent implementation.

Introduction

Background

FDA's Center for Devices and Radiological Health (CDRH) regulates medical devices. Through MDUFA, the FDA collects fees from manufacturers to improve the efficiency and effectiveness of medical device reviews. The current MDUFA V agreement establishes performance goals and implements program enhancements for fiscal years (FY) 2023 through 2027. The **TAP Pilot** is a voluntary program within MDUFA V that aims to increase access to high quality, safe, and effective medical devices by improving Breakthrough device Innovators' strategic decision-making. The TAP Pilot executes its vision with five objectives (detailed in MDUFA V), that aim to achieve the intended outcomes outlined in **Figure 1** below.

Summary of TAP Pilot Objectives

Enhanced Experiences for Participants and FDA Staff: Improved satisfaction with the collaborative, solutions-focused approach to device development and regulatory engagement with FDA and voluntary interactions with external stakeholders (non-FDA parties).

Enhanced Strategic Decision-Making: Better-informed product development decisions through earlier risk identification, assessment, and mitigation strategies.

Clearer Expectations: Improved alignment and understanding of evidence generation requirements between FDA and Innovators.

Higher Submission Quality: Elevated premarket submission quality resulting from collaborative expectation-setting and early engagement.

Improved Review Efficiency: Streamlined premarket review processes with more timely premarket interactions and enhanced efficiency.

Figure 1: Summary of TAP Pilot objectives as described in the MDUFA V commitment letter.

TAP Pilot Implementation

The TAP Pilot is implemented through a phased-enrollment approach over the duration of MDUFA V - fiscal years (FY) 2023-2027. Each year provides the option of increasing the number of devices and participating Offices of Health Technology (OHTs) based on capacity, while maintaining continuity for existing devices in the Pilot. **Figure 2** below details how the TAP expansion timeline has been, and continues to be, implemented across fiscal years:

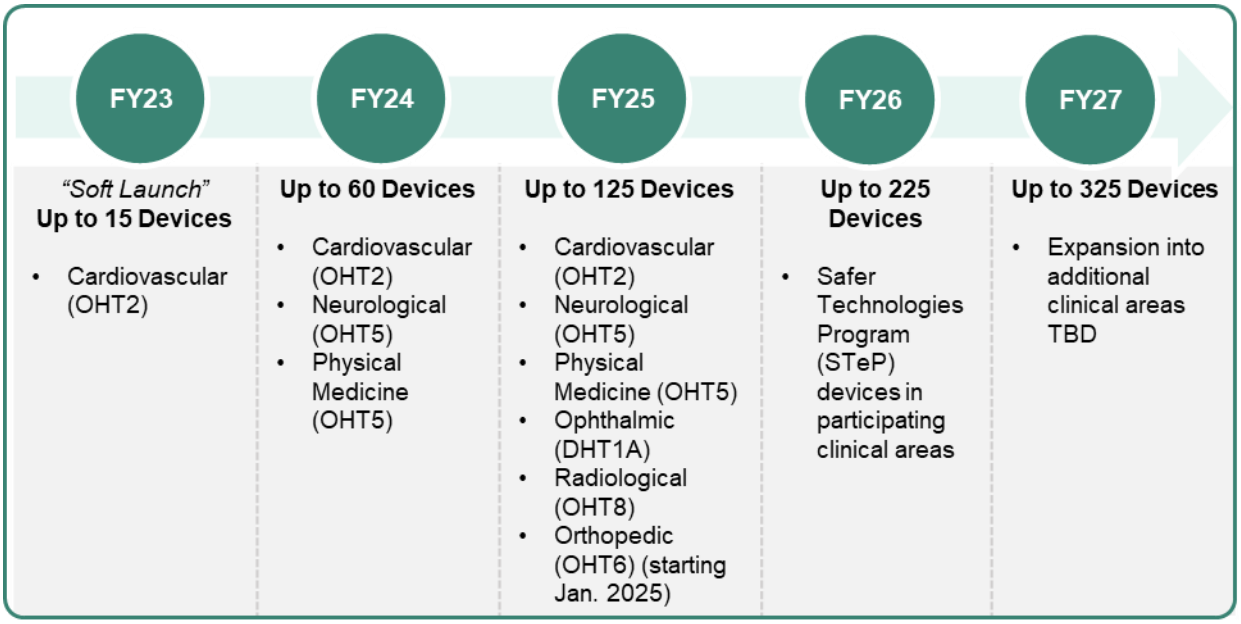

Figure 211: MDUFA V details the phased implementation of the TAP Pilot through FY2027, with optional increases in number of devices and OHTs.

Enrollment

The TAP Pilot includes the following summarized enrollment criteria[3]:

- Devices with a granted Breakthrough designation
- Devices early in their device development process (e.g., have not initiated a pivotal study)
- No pre-submissions related to the device were submitted after having received Breakthrough designation
- *Note: Starting in FY2026, devices that have been included in the Safer Technologies Program (STeP) and that fall under the review jurisdiction of the divisions/offices are also eligible.*

There is a limit of one device, per innovator, per fiscal year, on a first-come, first-served basis until the annual device limit is reached. Devices regulated by the Center for Biologics Evaluation and Research (CBER) and combination products are currently outside the scope of the Pilot.

[3] U.S. Food and Drug Administration TAP Enrollment Criteria: https://www.fda.gov/media/158308/download

TAP Stakeholders

A core element of the TAP Pilot is to take a more adaptive approach of interacting with the MedTech industry, encouraging collaboration and strategic engagement across various stakeholder groups. Key stakeholder groups participating in the TAP Pilot are provided below:

- **TAP Innovators:** Medical device companies enrolled in the TAP Pilot.
- **TAP Advisors:** FDA staff who coordinate proactive and strategic engagement between FDA, Innovators, and non-FDA parties. Their expertise and guidance help participants navigate the program effectively and contributes to key outcomes like more timely premarket interactions and improved strategic planning.
- **Non-FDA Parties:** Entities from the MedTech ecosystem such as patient organizations, medical specialist societies and associations, and reimbursement experts and payers. They may engage on voluntary interactions with TAP Innovators to provide early insights and inputs, working to improve the likelihood that their device ultimately reaches patients.
- **FDA Review Teams:** Teams of highly skilled CDRH staff who provide regulatory expertise across a range of topics and serve as the primary providers of regulatory feedback to Innovators. Through TAP interactions they deliver written and verbal feedback to help guide device development and regulatory strategy.

Program Enhancements Since the Launch of the Pilot

Throughout the assessment period, the TAP Pilot continued to evolve based on informal data collection by TAP Advisors, continuously working to improve programmatic challenges and solidify best practices. Key enhancements to the TAP Pilot are detailed below:

- **Engagement Plans:** An internal tool, developed and implemented by TAP Advisors, that organizes FDA and Innovator interactions by priority and upcoming submission milestones. At the initiation of each TAP file, this tool supports a structured engagement planning process involving Innovators, FDA review teams, and TAP Advisors determining future deliverables, timelines, and planned non-FDA engagements with payers, providers, and patient groups.
- **Payer Collaboration:** TAP Advisors worked with the Centers for Medicare & Medicaid Services (CMS) to better understand coverage and evidence decision processes. TAP Advisors set up structured engagements with commercial payers to discuss coverage development timelines and evidence requirements and launched TAP's Payer Horizon Scanning initiative, which convened FDA and payer medical directors to discuss emerging technologies and future coverage considerations.

*"TAP has created a meaningful channel for payors to engage early in the device development process. Through Horizon Scanning and structured dialogue, we've been able to **anticipate future technologies, align on evidence needs, and support more predictable coverage pathways.**"*
-Commercial Payer

Figure 3: Commercial payer feedback highlighting the meaningful engagement channels the TAP Pilot has created and facilitated.

*"We are able to get **insights on important new technologies**... We were also able to engage in a conversation with the FDA and provide payer perspectives that may be helpful to companies in their product development. In particular, we were able to **provide feedback on the evidentiary needs and other requirements to better ensure that the companies will be successful in gaining reimbursement for their new products**."*
-Commercial Payer

Figure 4: Commercial payer feedback highlighting the mutually beneficial exchange of ideas that the TAP Pilot provides for non-FDA parties and Innovators.

- **Broaden External Partnerships:** As of August 2025, 67 organizations are collaborating via TAP (per the TAP website) to provide TAP Innovators with strategic input on their innovative devices. TAP formed new, and built upon existing, CDRH relationships with professional societies and patient organizations to inform patient and clinical adoption and coding discussions. Coordination was also expanded with other federal partners, including the Department of Veterans Affairs (VA) and the National Institutes of Health (NIH), to align on shared innovation priorities.[4]

Together, these enhancements reflect the ongoing evolution of the TAP Pilot as staff refined processes and strengthened coordination to support sustained program growth.

Methodology and Data Collection

Overview

This assessment aims to measure TAP Pilot objectives, evaluate desired outcomes and impacts, and identify opportunities for improvement. From October 2023 to August 2025, a range of data collection methods were used, including surveys, interviews, observations, and data review across 95 TAP Innovators and 73 Non-FDA Parties. Assessment metrics are described in **Figure 5** below.

Process Metrics	• Percent of teleconferences with TAP Pilot Participants 14 days of the request • Percent of written advice on biocompatibility and sterility topic(s) within 21 days of the request • Percent of written feedback on requested topic(s) other than biocompatibility within 40 days of the request
Medium Term Outcome Metrics	• Overall satisfaction with TAP Pilot • Satisfaction with timeliness, frequency, quality and efficiency of interactions with and written feedback from FDA • Satisfaction with timeliness, frequency, quality and efficiency of interactions with and written feedback from non-FDA stakeholders facilitated by FDA (if utilized)
Early Impact Metrics	• Clearer expectations regarding evidence generation • Enhanced strategic decision-making during product development • Higher premarket submission quality • Improved development timelines

Identification of opportunities for improvement within the TAP Pilot

Figure 5: The assessment examines metrics across three categories: process, medium-term outcomes, and early impact.

[4] Both Commercial Payer quotations were collected through TAP Advisor interactions and not the assessment's systematic data collection framework.

Assessment Plan

This assessment applies a mixed-methods approach, integrating and analyzing data from multiple sources to provide a well-rounded view of TAP Pilot successes and areas for improvement. The assessment incorporated the following types of analysis:

- **Descriptive Analysis:** Summarized key metrics and trends, offering a clear snapshot of current performance and further insights about what may drive these metrics.
- **Longitudinal Analysis:** Examined changes over time to assess correlation, track progress, or identify persistent improvement opportunities.
- **Thematic Analysis:** Identified and interpreted patterns within qualitative data that provided granular context to key metrics and trends identified with quantitative data.
- **Root Cause Analysis:** Systematically identified underlying issues contributing to key challenges, enabling the development of targeted and sustainable improvement opportunities.

Data Collection Methods and Participant Selection

The assessment applied five data collection tools to enhance validity of the findings, capture various perspectives, and compensate for potential limitations. All Innovators enrolled in the TAP Pilot were invited to participate voluntarily, with assurance that their participation would not influence their engagement in the program.

Table 1 below details the data collection tools, frequency, and number of records/respondents for each:

Table 1: Data Collection Tool Details

Data Collection Tool	Frequency	Respondent Pool	Number of Records or Respondents
Customer Satisfaction (CSAT) Survey	Administered two waves, nine months apart to Innovators and non-FDA parties	209 surveys administered	148 survey responses
Participant Interviews	Conducted two waves, eight months apart to Innovators and non-FDA parties	74 interviews solicited	54 interviews conducted
Meeting Observations	Observed meetings between FDA and Innovators	988 documented meetings	82 interactions observed
Pulse Surveys	Administered to Innovators after completed formal TAP interactions across an eight-month period	96 surveys administered	34 survey responses
Administrative Data, Document, and Record Review	Routinely refreshed and analyzed internal FDA systems data across the period of the assessment	5 databases and systems data analyzed	

At the end of the assessment period, 95 Innovators were enrolled in the TAP Pilot for an average of 15 months, with variation due to the phased implementation of the Pilot:

- 32% (30) were enrolled for 6 months or less
- 20% (19) were enrolled for 7 to 12 months
- 43% (41) were enrolled for 13 to 24 months
- 5% (5) were enrolled for over 24 months

Limitations

A few existing limitations presented challenges to uncovering definitive evidence for assessing the outcomes of the TAP Pilot. Below in **Table 2** are three of the key limitations identified, along with explanations of the constraints and the mitigation strategies applied to reduce their impact. Additional limitations and external factors are found in the Appendix.

Table 2: Key Limitations and Mitigation Strategies

Limitation	Mitigation Strategy
TAP Pilot Maturity: The TAP Pilot is in its early, formative phase, with many systems, processes, and outcomes still evolving. Ongoing adjustments and shifting resources limit the reliability and generalizability of assessment results.	This assessment focuses on process and early outcomes (e.g., Innovator sentiment) to highlight early successes and provide as a gauge for longer term outcomes.
Length of Total Product Life Cycle: Many of the intended outcomes of the TAP Pilot (e.g., submissions, approvals, market entry) may take several years to fully materialize as the product life cycle is a lengthy process. With data collection ending in August 2025, the assessment timeframe does not allow for full measurement of long-term impact or causality.	This assessment uses early impact metrics, proxies, and case studies to show evidence regarding the likelihood of achieving mid to long term outcomes.
Voluntary Pilot Participation: Both participation in the Pilot and our data collection (e.g., surveys, interviews, observations) were voluntary, which may introduce self-selection bias. Those who chose to participate may be more engaged, more satisfied, or have stronger opinions compared to those who did not opt to respond. This may cause findings to not be fully representative of the broader population of stakeholders, particularly those who are less engaged or face barriers to participation.	The assessment team employed strategies to encourage broad and diverse participation through reminder messages, flexible scheduling, and clear, welcoming language. Demographic and role data were reviewed during the analysis to assess representativeness and identify any notable gaps.

Key Findings

The key findings of this assessment reflect the process, medium-term, and early impact metrics identified in the assessment planning phase. They are grounded in a thorough analysis of all

data collected throughout the assessment period. Each section highlights the key metrics and provides a detailed analysis of the supporting data.

Process Metrics

MDUFA V Quantitative Performance Goals

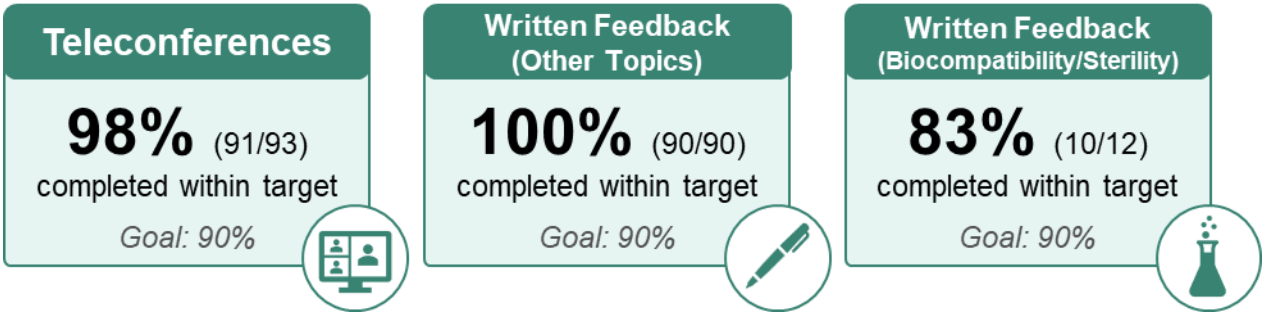

Figure 6: The MDUFA V quantitative goals assess amendment types and their associated timeframes for completion.

Since its implementation, the TAP Pilot has demonstrated significant engagement and operational success in meeting participant needs and exceeding targets for two of the three quantitative goals, shown in **Figure 6** above. The three performance goals represent the three amendment types available within the TAP Pilot. An amendment is a requested and documented interaction with FDA specific to regulatory topics, tracked using an existing CDRH amendment mechanism to align with MDUFA V quantitative performance metrics. TAP exceeded quantitative goals for the amendment types that accounted for 94% of all Innovator requests for formal FDA feedback.

Detailed Analysis

Meeting MDUFA Timeline Commitments*:* The program has demonstrated solid performance in meeting established deadlines, though timing varies by review type. As of August 15, 2025, there have been a total of 195 TAP amendments completed across all 95 participating Innovators. The 90% MDUFA V feedback timeliness goals for teleconferences and written feedback on general topics were met. However, the 90% timeliness goal for written feedback on biocompatibility/sterility topics was narrowly missed due to minor administrative errors[5], with 10 out of 12 responses completed on time.

Teleconferences were scheduled to occur by the date requested by the Innovator or within 14 days. Nearly half (48%) of the teleconferences took place before day 14. Biocompatibility and sterility reviews tend to be completed later, with most finishing on the final day (day 21) or after, and only one amendment (8%) completed early on day 20. These timing differences reflect varying complexity and resource needs across review types.

When looking at data isolated to FY2024, all targets were met, with 97% (29/30) of teleconferences, 100% (3/3) of written feedback on biocompatibility and sterility, and 100%

[5] The two delayed responses were due to minor administrative errors: one instance where feedback was provided during a teleconference but not formally signed out until day 22, and another caused by a misclassification at upload by the Document Control Center, who did not recognize the request as biocompatibility-related.

(39/39) of written feedback on other topics completed on time. In FY2025 (as of August 15, 2025), 98% (62/63) of teleconferences, 100% (51/51) of written feedback on other topics, and 78% (7/9) of written feedback on biocompatibility and sterility topics (this target was not met) completed on time.

These frequent interactions with FDA help Innovators proactively address potential regulatory concerns and directly support MDUFA V requirements by focusing discussions on key development milestones and regulatory pathway decisions. This depth of engagement lays the groundwork for more efficient regulatory reviews by clarifying expectations early, potentially reducing the need for multiple review cycles and supports faster, more predictable processes planned in MDUFA V.

Medium Term Outcome Metrics

Innovator Satisfaction Overall

This assessment used the Net Promoter Score (NPS)[6], a standardized metric commonly used to measure customer experience and program loyalty. The assessment used NPS as measure of satisfaction; by asking participants how likely they are to recommend the program to others. Independent Benchmarks from Qualtrics XM Institute place industry average NPS scores between 15 and 35.[7] While there is no direct industry comparison and data collection methods differ (audience, channel, timing), these benchmarks are used as context rather than a direct comparison. The TAP Pilot achieved an NPS of 83, indicating exceptionally high satisfaction and strong Innovator endorsement (see **Figure 7**).

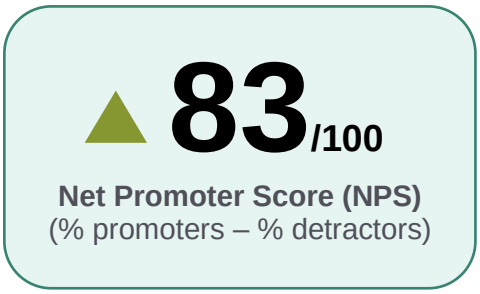

Figure 7: The Net Promoter Score indicates overall satisfaction.

Detailed Analysis

Overall Program Value: In interviews, Innovators consistently emphasized the importance of the TAP Pilot for their devices and highlighted the crucial coordination and guidance provided by TAP Advisors and review teams. Direct observations of interactions showed collaborative meetings between FDA and Innovators, with most Innovators expressing sincere appreciation for FDA's support.

Continuous Program Enhancement by CDRH: Longitudinal analysis across the two survey waves showed a six-point NPS increase. When controlling for repeat participants, satisfaction levels remained unchanged, suggesting that continuous program improvements (e.g., improved onboarding and processes) may have successfully enhanced satisfaction for new participants while maintaining high levels for longer-tenured Innovators.

[6] Harvard Business Review, The One Number You Need to Grow; Qualtrics, What is NPS?
[7] Qualtrics XM Institute, 2024 Industry Benchmarks

*"So we got TAP for our first device… **we will definitely want to use TAP for additional devices,** in the future"*
-Innovator, Interview

Figure 8: Innovator feedback highlighting interest in using TAP for additional devices.

Interest in Program Expansion: The program's success has created strong demand for expansion, with Innovators expressing interest in enrolling additional devices, as shown in **Figure 8**. Non-FDA parties also emphasized the importance of programs like TAP in supporting small companies and advancing emerging technologies.

Innovator Satisfaction with FDA Interactions

The TAP Pilot has facilitated extensive engagement between Innovators and FDA, with a total of 1,240 documented interactions. Across this same time frame, the Pilot averaged 54 interactions per month. These interactions included engagement planning meetings, regulatory discussions with FDA review teams, kickoff meetings, and touch base meetings. Touch base meetings served as check-ins between FDA and Innovators to plan future interactions, discuss Innovators' strategies for collaborating with FDA SMEs, request feedback, and explore opportunities for connecting with non-FDA parties.

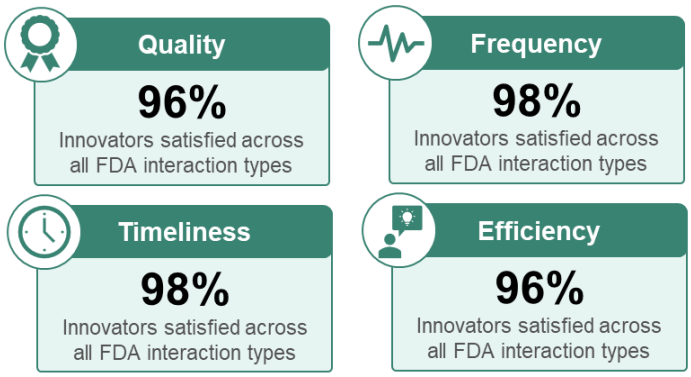

Figure 9: Per the MDUFA V commitment letter, satisfaction with FDA interactions was assessed across quality, frequency, timeliness and efficiency.

Across a wide range of interactions, 96% of Innovators reported being satisfied or very satisfied with their FDA engagement on quality, timeliness, frequency, and efficiency shown in **Figure 9**. This exceptionally high satisfaction highlights the value Innovators place on the sustained, collaborative dialogue enabled by the TAP Pilot. It also reinforces positive perception of the program's approach of providing regular, solutions-focused engagement.

Detailed Analysis

This strong satisfaction was seen across both waves of the satisfaction surveys, including among repeat participants. In addition, pulse surveys conducted immediately after interactions reinforced these findings, yielding an average satisfaction score of 94 out of 100.

*"Feedback was timely, and **issues raised and discussed were insightful and helpful in moving to next steps**"*
-Innovator, Pulse Survey

Figure 10: Innovator notes actionable feedback received from TAP interactions.

***Quality**:* Innovators consistently praised the complete and actionable nature of FDA feedback, with 89% of observed interactions providing constructive guidance. They also described TAP Advisors and review teams as excellent sources of high-quality support, noted in **Figure 10**.

***Frequency**:* Most Innovators emphasized that early and frequent interactions were among the most valuable aspects of the TAP Pilot, helping them build stronger relationships and better understand FDA perspectives. In 90% of observed meetings, participants felt comfortable asking questions and engaging in open dialogue, underscoring the importance of frequency in fostering collaboration.

***Timeliness**:* 40% of interviewed Innovators positively highlighted the Pilot's speed and quick turnaround times. Participants noted substantial time savings, receiving feedback within 14 to 40 days compared to 70 days for the traditional Q-submissions, which also enabled them to move multiple submissions forward in parallel.

***Efficiency**:* 87% of interviewed Innovators cited improved efficiency through enhanced access to direct dialogue with Lead Reviewers and subject matter experts, as evidenced by the case study detailed in **Figure 11**. This access built stronger relationships, improved communication, and made interactions more productive and collaborative than traditional regulatory pathways.

Case Study: FDA Collaboration Accelerates Device Development

SITUATION: An Innovator **discussed their written feedback received** during a TAP teleconference, with multiple FDA subject matter experts participating including biocompatibility, electrical safety, and human factors reviewers.

OUTCOME: Each **FDA expert actively contributed specialized feedback** from their domain, with the biocompatibility reviewer suggesting specific test protocols, the electrical safety expert recommending temperature controls, and the human factors specialist providing risk mitigation strategies. The **Innovator asked detailed follow-up questions, and FDA experts built upon each other's recommendations** to provide integrated guidance that addressed the device's complex technical requirements.

IMPACT: This **collaborative and efficient approach accelerated the device development timeline** by providing clear and actionable outcomes from interactive discussions.

Figure 11: Case study highlights the collaborative nature of TAP helping an Innovator accelerate device development through subject matter expert input, discussing detailed written feedback.

Innovator Satisfaction with Non-FDA Stakeholder Interactions, Facilitated by FDA

Through TAP, the FDA has facilitated 117 engagements between Innovators and non-FDA parties during the assessment period. A total of 35 Innovators either requested or engaged in these types of interactions. Among these interactions:

- 36 involved **provider-related** topics
- 27 focused on **payer-related** topics, and
- 21 involved **patient-focused** discussions[8]

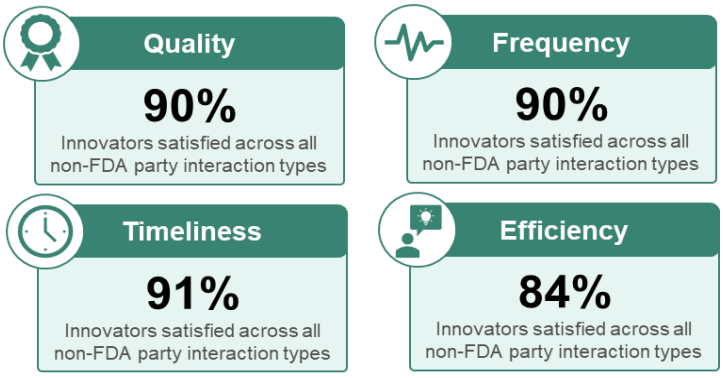

Figure 12: Per the MDUFA V commitment letter, satisfaction with non-FDA party interactions was assessed across quality, frequency, timeliness and efficiency.

Innovators reported high satisfaction with the quality, frequency, timeliness, and efficiency of TAP interactions, as shown in **Figure 12**, with no dissatisfaction recorded (only neutral: neither satisfied nor dissatisfied). They valued the

[8] The remaining 33 discussions included other topics.

opportunity to engage diverse stakeholders early in the development process. Non-FDA parties also expressed positive views, emphasizing the importance of programs like TAP in supporting innovative devices and creating collaborative discussions.

Detailed Analysis

Analysis of Innovator satisfaction with non-FDA party interactions showed consistent results over time, with one exception: declining satisfaction with the frequency of payer and payer subject matter expert (SME) engagement[9], suggesting an area for improvement. Below is a breakdown across quality, frequency, timeliness, and efficiency.

> *"Paid consultants...often try to sell themselves.* ***The information we got from the TAP interactions was more genuine and to the point. We felt we could rely more on the information*** *being passed to us, rather than the ones we engaged ourselves separately."*
> *-Innovator, CSAT Survey*

Figure 13: Innovator highlights the unbiased feedback received from non-FDA parties through TAP facilitation.

Quality*:* Innovators noted the high-quality feedback and expertise provided by non-FDA parties through the TAP Pilot as shown in **Figure 13**. Among those with prior experience engaging non-FDA parties outside the Pilot, 100% reported that TAP-facilitated interactions were equal to or better than their previous experiences, noting that non-FDA parties offered deeper expertise in specialized areas and provided more comprehensive guidance.

Frequency*:* While 85% of Innovators felt the frequency of interactions with non-FDA parties was appropriate, 15% reported they occurred too seldom.

Timeliness*:* 71% of Innovators emphasized that FDA's credibility and influence gave them access to high-quality non-FDA parties and helped secure timely responses that might otherwise be overlooked. Data show that TAP delivers a level of access and coordination not easily replicated outside of the program.

Efficiency*:* Innovators expressed that FDA involvement supported efficient connections, noting that TAP Advisors were able to quickly identify relevant non-FDA parties based on the Innovator needs. This approach helped Innovators focus on the non-FDA parties most critical to advancing their device strategies.

Early Impact Metrics

Improved Expectations Regarding Evidence Generation

96% of Innovators agree that their organization has a **better understanding of FDA's expectations regarding evidence generation**

The TAP Pilot has made notable progress in clarifying what is needed for evidence generation and setting clear expectations for Innovators. Feedback from the satisfaction survey and interviews shows that Innovators now have a stronger understanding of the types of evidence

[9] Payer SME utilization was impacted by changes in the use of contractors during the assessment period.

the FDA is seeking, ranging from what should be demonstrated in clinical studies to the level of detail expected in FDA submissions.

Detailed Analysis

Innovators' understanding of evidence generation as part of their regulatory strategies improved over the course of the TAP Pilot. Among participants who responded to both the 2024 and 2025 surveys, agreement increased by 23 percentage points, rising from 64% to 87%. This suggests that the program's enhancements may be driving better outcomes in this area.

Qualitative data showed that the TAP Pilot's framework of early and frequent interactions with FDA helped provide validation of ideas, enhanced regulatory guidance, and a deeper understanding of FDA perspectives.

> *"Initially, we were thinking we would do prospective studies, and then we discussed the possibility of retrospective studies only. Seeing how open they are, those discussions have enabled us to* ***put in the submission [estimated] even more than one year in advance.*** *Because, if we don't have to do a prospective study, and we understand that the requirements might be satisfied with the retrospective study, that* ***cuts a lot of processing time*** *in preparing for the submission."*
> *-Innovator, Interview*

Figure 14: Innovator received strategic feedback through TAP that helped avoid unnecessary studies, saving time and money.

Strategic Validation Through Early Dialogue: Interactive discussions within the TAP framework enabled Innovators to validate their evidence generation strategies before committing significant resources. Over half (53%) of interviewed Innovators highlighted the ability to validate evidence generation strategies as a benefit. Early validation helped them avoid costly missteps in development pathways and supported more strategic allocation of resources, as noted in **Figure 14**.

Enhanced Regulatory Guidance: Observed interactions consistently demonstrated high levels of collaboration, with FDA staff providing concrete examples of evidence generation requirements and offering specific guidance to help Innovators navigate complex regulatory requirements. This hands-on guidance went beyond traditional regulatory interactions by offering practical frameworks for thinking through evidence development.

Direct Access Improves Technical Understanding: The program's emphasis on direct dialogue with Lead Reviewers and subject matter experts has proven valuable for both building relationships and technical understanding. This access allows for nuanced discussions about evidence requirements that would be difficult to achieve through traditional written submissions alone.

Enhanced Quality of Strategic Decision-Making

93% of respondents reported that TAP Pilot interactions had a **positive effect on their organization's strategic decision-making**

Innovators expressed strong positive sentiment about their strategic decision-making capabilities. More than half of interviewed Innovators specifically emphasized the TAP Pilot's value in de-risking device development by providing clarity on both regulatory and non-regulatory pathways. This clarity enabled them to make more confident decisions earlier in the process and avoid potentially costly development missteps.

Detailed Analysis

Data demonstrates that Innovators believe the TAP Pilot significantly enhances their strategic decision-making capabilities. This sentiment has grown stronger over time, with a seven-percentage point increase overall and a three-fold rise in the number of Innovators reporting "extreme confidence" in strategic decision-making among those who took the survey both in 2024 and 2025. Benefits to regulatory strategy were reported by 93% of respondents, compared to 49% of respondents that noted benefits to their commercialization strategy.

Collaboration with FDA: 87% of Innovators noted that the level of collaboration, driven by the TAP Pilot, effectively supported how they made strategic decisions across clinical trial design, hiring, and resource allocation. Across observed interactions, collaboration between Innovators and FDA was high quality, with discussions characterized as friendly, participants feeling comfortable asking questions and FDA often providing clear and actionable information, as noted in **Figure 15**.

"Feedback was thorough and timely. The information raised meaningful points for the team to consider prior to conducting testing. ***This will help to avoid major issues during the marketing submission."***
-Innovator, Pulse Survey

Figure 15: Innovator notes the strategic, timely feedback helps avoid and mitigate for errors and risk.

Access to High Quality Technical Advice: Observations from TAP meetings showed that FDA consistently provided relevant examples and shared published guidance to support Innovator decision-making. When follow-up questions or differing views emerged during interactions, 80% of those instances reached a clear resolution regarding technical issues or regulatory pathway decisions. Additionally, approximately 80% of meetings ended with defined next steps for either the Innovator or FDA, helping to maintain momentum and alignment on the device's overall strategic direction.

FDA's Credibility and Connections Across Non-FDA Parties: Observed interactions show that FDA consistently helps facilitate early connections between Innovators and non-FDA parties during device development. Among Innovators who engaged with non-FDA parties, 88% reported satisfaction with the feedback received on non-regulatory topics that supported their strategic planning.

Higher Quality Pre-market Submissions

96% of respondents report feeling **confident** (very confident, somewhat confident, or slightly confident) that their **organization will achieve FDA marketing authorization**

The impact of TAP on the quality of Innovator marketing applications is a long-term outcome that we are not yet able to directly measure. To assess potential progress toward this objective, we have implemented leading indicators and short-term success metrics. These include Innovator sentiment, confidence levels, and the extent to which devices are being de-risked

through Pilot engagement. Notably, Innovator confidence has grown over time. 64% of Innovators who responded to the survey in both waves reported the same or increased confidence in receiving FDA marketing authorization on the first attempt in 2025 compared to 2024.

Detailed Analysis

Innovator sentiment regarding the TAP Pilot's ability to de-risk device development serves as a key leading indicator of regulatory confidence and broader success across the device approval process and commercial lifecycle, as noted in **Figure 16**.

*"[TAP] has really helped us to **increase the possibility that this is not just a technology that works in the lab, but also will be adopted by clinicians, by the commercial perspective.** That is really important, and otherwise we're really risking our investment into very expensive clinical studies."*
-Innovator, Interview

Figure 16: Innovator notes that TAP helped them consider the broader MedTech adoption of their device.

Early Engagement De-Risks Device Development: The TAP Pilot's proactive engagement model is positively influencing Innovator perceptions of regulatory risk. Among interviewed participants, 29% reported a reduced fear of major deficiencies or rejections due to implementation of what they've learned through interactions facilitated by TAP. The early intervention approach allows for timely course corrections, helping Innovators avoid costly regulatory missteps. This benefit was identified by over half of interviewed participants (53%) as one of the most valuable aspects of the program. Frequent discussion of regulatory topics contributes to increased Innovator confidence.

Clarity, Collaboration, and Communication Increases Confidence: The TAP Pilot's structured, step-by-step approach helps de-risk device development by providing greater regulatory clarity and strategic alignment. This methodical engagement produced measurable benefits. 36% of interviewed Innovators reported gaining strategic clarity that will lead to more polished submissions, while 35% of survey respondents noted successful alignment with FDA on critical steps toward marketing authorization. In addition, half of interviewees shared that the step-by-step validation process with FDA increased their overall confidence.

Improved Development Timelines

Many Innovators reported both **anticipated and actual cost and time savings** as a result of their participation in the TAP Pilot

Improved efficiency in the pre-market process and accelerated device development timelines are anticipated long-term impacts of TAP that cannot yet be directly measured. To assess early progress toward these goals, we identified leading indicators such as Innovator perceptions of the TAP Pilot's value in shaping their overall device development plan and whether they believe the program has saved them time and money. Across both waves of data collection, Innovators consistently expressed the value of the TAP Pilot, with many offering estimates of cost and time savings due to their participation. However, due to the long-term nature of the Pilot, some Innovators noted that it is still too early to fully assess actual savings.

Detailed Analysis

Innovators consistently highlighted the TAP Pilot's impact on the speed and efficiency of their pre-market review process, with many Innovators pointing to cost and time savings enabled by early and frequent feedback. Innovators also reported FDA facilitation significantly improves both speed of access and quality of non-FDA party engagement compared to independent company outreach.

***Direct Cost and Time Savings**:* Approximately 40% of Innovators interviewed described tangible financial and time-related benefits, with one example detailed in **Figure 17** below. Several estimated that TAP helped them avoid tens to hundreds of thousands of dollars in unnecessary testing and studies by providing early strategic guidance. Some Innovators estimated they saved six months to one year, while others believed TAP accelerated their path to market by more than one year.

Process Speed and Flexibility: Innovators frequently compared TAP's interaction model with traditional Q-Submissions, noting that TAP typically provides written feedback within 14 to 40 days, significantly faster than the 70 days associated with Q-submissions. However, it is important to acknowledge that this comparison is not entirely one-to-one. The TAP Pilot includes a smaller set of devices and a more focused implementation, which allows for greater FDA reviewer capacity and quicker turnaround times than may be possible in a broader program.

Additionally, the TAP Pilot allowed for interactions to occur in parallel, enabling Innovators to address several topics simultaneously rather than sequentially. Observations of TAP meetings reinforced these findings, with FDA reviewers and Innovators jointly planning future meetings and establishing shared submission timelines. This structure fostered greater clarity and coordination, reducing delays, and encouraging more focused follow-up discussions. Overall, TAP created a rhythm of regular engagement that sponsors described as increasing predictability and momentum in their development process.

Case Study: Small Medical Device Company Accelerates FDA Understanding Through TAP Pilot

SITUATION: A medical device startup struggled with FDA communication, **receiving feedback that lacked actionable guidance for their submissions**.

OUTCOME: Through the TAP Pilot, the company engaged in monthly check-ins with their FDA review team and submitted targeted amendments to clarify regulatory requirements. They leveraged the **informal discussion format to ask detailed questions and receive comprehensive written responses that explained the reasoning** behind FDA positions.

IMPACT: The company achieved an **estimated 6-12 months of time savings and over $100,000 in consultant cost savings** by eliminating the traditional 70-day Q-submission goal. They gained precise understanding of FDA expectations, enabling confident submission of amendments with clear regulatory pathways.

Figure 17: Case study details an Innovator achieving an estimated 6-12 months of time savings and over $100,000 in cost savings from feedback received through the TAP Pilot.

Improvement Opportunities

The FDA has made significant strides in deploying the TAP Pilot, dedicating substantial time and resources to collaborate with Innovators and non-FDA parties to accelerate medical device development and improve patient access to safe, effective technologies. While feedback from participants has been highly positive, it also highlighted areas where operations can be strengthened. Our root cause analysis revealed two key factors contributing to current challenges: the program's rapid launch and expansion, and ongoing resource constraints. These root causes affect three interconnected areas: **process standardization**, **communication**, and **program scalability**, which form the basis of the improvement opportunities described in **Figure 18** below.

Summary of Improvement Opportunities

1. Standardize Processes and Improve Documentation
Creating standardized processes and documentation will reduce workflow variability, ease administrative burden, and provide clearer, more predictable pathways for participants.

2. Strengthen Communication and Education Across TAP
Improving communication between FDA, program participants, and the broader MedTech community will align expectations, foster responsive feedback loops, and elevate the Pilot's profile.

3. Address Program Maturity and Scalability
Building on operational foundations and transparent communication will help formalize long-term strategies, expand infrastructure, and integrate lessons learned to sustain growth.

Figure 18: Three progressive improvement opportunities were developed based on common pain points and opportunities revealed through the assessment.

Together, these three improvement opportunities present a cohesive strategy to strengthen day-to-day operations, improve coordination among participants, and build the foundation for long-term scalability.

Improvement Opportunity Framework

The framework shown in **Figure 19** illustrates how assessment findings were translated into structured opportunities for improvement. The following sections outline the key pain points identified and recommended opportunities for improvement developed to address them.

Key Pain Points Identified
Pain points are issues identified by Innovators or observed during the assessment that limit TAP's effectiveness in its current form.

Opportunities for Improvement
Broad themes for improvement developed from the identified pain points. These define focus areas and guide specific recommendations for strengthening the TAP Pilot within FDA's authority.

Figure 19: Framework illustrating how assessment findings were synthesized into structured opportunities for improvement.

Improvement Opportunity #1

Standardize Processes and Improve Documentation

To strengthen operations and support smoother implementation, the first improvement opportunity centers on increasing process standardization and documentation. Implementing comprehensive process standardization and documentation will transform both the immediate operational efficiency and long-term strategic impact of the TAP Pilot program. Addressing these issues will improve day-to-day efficiency and enable better knowledge transfer, stronger training protocols, and more effective cross-functional collaboration.

Key Pain Points Identified

Define Roles and Responsibilities: Innovators and non-FDA parties noted a lack of clarity around their specific role when it came to the engagement process, including generating meeting materials, interaction documentation and minutes, and follow-up processes.

Consistency in Processes: At times, the variability in processes left Innovators and non-FDA parties confused about how to appropriately engage and general follow-up procedures.

*"We don't **have meeting summaries**. This is a drawback... it would be nice to have meeting summary to remember what we talk about (in touchbases). **Sometimes I do not have all the notes on my end**…if the program provided meeting summaries it would be very useful."*
-Innovator, Interview

Figure 20: Innovator indicates that the level of information provided could outpace the resources they have available to address feedback provided by TAP.

Need for Standard Documentation: Innovators expressed the desire for clearer and more consistent documentation when engaging with FDA and non-FDA parties. They emphasized the importance of structured follow-up steps, defined responsibilities, and timely documentation of meetings. Some Innovators reported positive experiences using TAP documentation such as engagement plans, while others found the available materials limited or unclear.

Opportunities for Improvement

The pain points reveal an opportunity for enhanced standardization of TAP processes, as well as additional clarity on roles and responsibilities, through improved resources. This can improve Innovators' and non-FDA parties' understanding of how to engage with the program, each other, and maximize their experience.

Standardize Internal Operations: The variation in clarity across different interaction types and the need for more consistent guidance provides an opportunity to formalize current key workflows and clarify roles and responsibilities. Standardizing internal operations, templates, and engagement protocols can provide a more predictable and transparent experience for Innovators and non-FDA Parties.

Enhance Documentation*:* Innovators experiencing ongoing uncertainty about progress, despite documented next steps, highlights the need for improved resource materials and guiding documents to improve understanding. Enhancing existing resource materials and

documentation will help TAP Pilot participants better understand the TAP processes and expand their understanding of how to engage with the program and maximize the value.

Improvement Opportunity #2

Strengthen Communication and Education Across TAP

Building directly on strengthened internal procedures and documentation, the second improvement opportunity aims to enhance how the program communicates key information regarding expectations and processes. Educational materials and structured communication plans and protocols aligned with standardized processes can help the TAP Pilot provide clearer guidance and establish consistent feedback mechanisms. This supports stakeholders in receiving clear and helpful information that helps them realize greater value from their engagement.

Key Pain Points Identified

Unclear Scope of FDA Feedback: Some Innovators noted that FDA conversations through TAP can sometimes uncover additional technical considerations that expand project requirements beyond the original scope, creating unexpected workload for resource constrained companies, as seen in **Figure 21**. With multiple subject matter experts providing input based on their specialized experience during TAP interactions, Innovators often struggle to distinguish between mandatory feedback that must be addressed versus advisory suggestions they can choose to implement.

> *"Help us prevent scope creep with too many meetings with the FDA. There is a risk of us having to do way too much simply by having too many conversations and opportunities for discussion with the FDA. This is helpful in doses but **could kill our company if we are expected to do everything under the sun as a result of conversing more frequently**."*
> *-Innovator, CSAT Survey*

Figure 21: Innovator indicates that the level of information provided could outpace the resources they have available to address feedback provided by TAP.

> *"It was shaky at the beginning, partly because we didn't ask, **partly because we weren't provided guidance**."*
> *-Innovator, Interview*

Figure 22: Innovator notes lack of guidance provided at the beginning of their time in the Pilot.

Other Innovators expressed a desire for more specific guidance during FDA interactions and felt uncertain after discussions, as evidenced by **Figure 22**. This may often reflect the inherent limits of informal interactions since FDA staff cannot provide definitive commitments without further data review.

Unclear Non-FDA Party Next Steps: Many Innovators felt unclear about next steps after initial interactions with non-FDA parties, often lacking clarity on who should follow up and how to sustain momentum. Some non-FDA parties also reported limited understanding of TAP's objectives and their role in engaging with Innovators.

Gaps in Innovator Expertise: While Innovators recognize the importance of this early-stage guidance, some noted their lack of capacity or understanding of how to engage at a level that

could meaningfully shape their device development strategy due to a lack of internal subject matter expertise. This challenge reflects a broader challenge beyond FDA's direct control.

Opportunities for Improvement

The pain points identified reveal opportunities for enhanced communication of expectations and supplemental educational materials. These will build on standardization of internal processes and resources to further strengthen participant engagement.

***Strengthen Communication and Information Sharing**:* Confusion between mandatory feedback and advisory suggestions, along with uncertainty following FDA and non-FDA interactions, indicates an opportunity to enhance how information is communicated and contextualized. Clearer communication protocols can help Innovators better understand the nature and scope of feedback they receive, while improved information sharing mechanisms can ensure all parties have appropriate context for their interactions.

Improve Education Materials: Limited Innovator expertise underscores the need for continued education and support. This creates an opportunity to expand educational materials covering both operational topics (such as roles and responsibilities) and technical areas (such as reimbursement and patient feedback). Strengthening these resources would help Innovators better use all aspects of the TAP Pilot, particularly non-FDA party engagements that inform decision-making for commercialization and market access planning

Improvement Opportunity #3

Address Program Maturity and Scalability

The TAP Pilot's rapid launch and expansion over the past two years has outpaced the development of supporting infrastructure, review team operations, and external stakeholder networks needed for sustained growth. While the key findings have indicated satisfaction with and positive early impacts of the TAP Pilot, pain points have revealed opportunities to strengthen foundational elements to support the ongoing scaling of the Pilot.

Building program maturity involves developing systematic approaches to resource management, expanding strategic partnerships, and creating scalable operational models to accommodate growth while maintaining quality. As the program transitions from pilot phase toward broader implementation, building on standardized processes and establishing mature operational frameworks will be critical for achieving its full potential impact on the total product lifecycle and supporting the diverse needs of the medical device innovation community.

Key Pain Points Identified

Unrealized Access to Non-FDA Parties: Several Innovators noted that the current pool of non-FDA parties may not fully meet the program's evolving needs, as seen in **Figure 23**. Some Innovators also emphasized the importance of formalizing access to the Centers for

*"There are all of these linkages that, on paper, exist between FDA and payers and CMS. **I'm just not sure how real or tangible those are**."*
-Innovator, Interview

Figure 23: Innovator unsure of the formalized relationship between FDA and CMS through TAP.

Medicare & Medicaid Services (CMS), given its central role in reimbursement decisions.

***FDA Resourcing Challenges**:* Innovators reported that ongoing resource constraints within the FDA have, at times, led to slower response times and less detailed feedback. Several participants noted that when review staff were unavailable or on leave, handoffs were inconsistent, resulting in delays and uncertainty about next steps. In addition, some expressed concern they may not receive the same responsiveness and level of interaction as the program scales up, compounded by external factors that affect resources.

Barriers for Small or Start-up Innovators: Limited time and funding often constrain smaller Innovators' ability to fully engage with TAP. Some noted that the program's collaborative framework is time intensive, requiring preparation for frequent interactions, while others said limited funding forced them to prioritize technical or regulatory milestones over broader strategic activities. As a result, many small Innovators struggled to participate in non-FDA party discussions, such as those with payers, providers, and patient groups, that are critical for market access planning and demonstrating broader value. This challenge may be amplified by TAP's intentionally broad enrollment criteria, which allows participation by Innovators at very early stages of development. While this inclusivity supports TAP's mission to reach a diverse range of Innovators, it also highlights the need for continued support mechanisms to help participants fully benefit from the program.

Opportunities for Improvement

The pain points identified reveal opportunities for improved program promotion and development of systematic tools and frameworks to support efficient engagement. These will support the scaling of the TAP Pilot to continue to build the non-FDA network as well as indirectly support Innovators in their independent search for funding opportunities In addition, with systematic tools in place, both FDA and Innovators can have efficient and effective engagement to better realize TAP benefits.

Strengthen Collaboration and Support Mechanisms: While continued outreach and communication about TAP's success stories remain important for expanding awareness and attracting new collaborators, there are also opportunities to strengthen engagement with non-FDA partners, particularly CMS and other parties critical to innovators' market access and reimbursement planning. As the program grows into new technology areas, maintaining and broadening these partnerships will help ensure the program continues to meet evolving innovator needs. In addition, enhancing support mechanisms for innovators, such as clarifying program expectations and participant responsibilities through improved website content or a pre-TAP orientation meeting, can help make sure innovators are well prepared to engage effectively and realize the full benefits of TAP participation.

Develop Systematic Tools and Frameworks: To address internal resourcing challenges and optimize engagement for resource-constrained Innovators**,** developing systematic tools and frameworks for data collection, best practices capture, and continuous improvement will enhance program efficiency. These tools can also optimize the timing and preparation for Innovator engagement, addressing current resource constraints and reducing burden on both FDA and Innovators while maximizing program benefits.

Innovator Cohort Improvements: To support continued productive and efficient engagement from Innovators with the Pilot offerings, the Pilot may benefit from refined enrollment criteria. Many Innovators noted variability in funding and available time in interviews, as well as differing level of experience in interacting with non-FDA parties. These challenges often affect the

Innovator's ability to fully engage with the Pilot in the most effective way, with some needing to delay engagement or narrow focus to one topic at a time. Therefore, updated enrollment criteria may target those Innovators that use the Pilot to its full potential, while also helping FDA manage internal resources effectively. Refined enrollment criteria may also help FDA regulate the growth and expansion of the Pilot, as Innovators progress through and are phased out of the Pilot.

Conclusion

This third-party assessment confirms that the TAP Pilot is not only meeting its primary goals, but creating a robust framework for innovative regulatory partnerships that has progressed how FDA collaborates with stakeholders across the MedTech industry.

The program's demonstrated success, facilitating over 1,240 interactions, strong performance against MDUFA V metrics, achieving a Net Promotor Score of 83, and delivering measurable improvements in Innovator confidence and strategic decision-making, validates the effectiveness of this collaborative TAP Pilot model. Most significantly, the data show promise of TAP in achieving impacts such as accelerating development timelines and improving efficiency, without compromising safety standards.

However, the assessment also reveals that the program's rapid expansion has outpaced supporting infrastructure development. The three identified improvement opportunities, process standardization, enhanced communication, and addressing scalability challenges, provide a clear roadmap for optimizing program effectiveness. By implementing these targeted enhancements, FDA can build upon TAP's strong foundation to create a more formalized and scalable framework and enable the program to accelerate patient access to safe and effective medical devices while sustaining the collaborative framework that drives its current achievements.

Figures and Tables

Figures

Tables

Appendices

1.1 Acronyms and Key Terms

Acronyms and specific terms are used throughout this report. The table below provides definitions and descriptions.

Table 3: Acronyms, Key Terms, and Definitions

Term	Definition
CARS	Center Ad Hoc Reporting System
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
CMS	Centers for Medicare and Medicaid Services
CSAT	Customer Satisfaction
CTS	Center Tracking System
EMC	Electromagnetic Compatibility
FDA	Food and Drug Administration
FDA Review Team	Team of highly skilled CDRH staff who provide regulatory expertise across a range of topics and serve as the primary providers of regulatory feedback to Innovators. Through TAP amendments, they deliver written and verbal feedback to help guide device development and regulatory strategy.
FY	Fiscal Year
HF	Human Factors
Innovator	Medical device company enrolled in the TAP Pilot.
ITR	Insight Time Reporting
KPI	Key Performance Indicator
MDUFA	Medical Device User Fee Amendments
NIH	National Institutes of Health
Non-FDA Party	Organizations or individuals from the MedTech ecosystem such as patient organizations, medical specialist societies and associations, and reimbursement experts and payers. They may engage on voluntary interactions with TAP Innovators to provide early insights and inputs, working to improve the likelihood that their device ultimately reaches patients.
NPS	Net Promotor Score
OHT	Office of Health Technology
OMB	Office of Management and Budget
Patient Non-FDA Party	Disease-specific patient advocacy groups and/or patient science subject matter experts.
Payer Non-FDA Party	Funders of health care services, SMEs with knowledge of fundamental pillars of device reimbursement (coding, coverage, and payment), health technology assessment methods, the business of healthcare or healthcare economics.
Provider Non-FDA Party	Disease/anatomy specific professionals and professional societies with knowledge of patient care pathways or who are involved with creating common procedural terminology and making recommendations, developing position statements, and/or clinical practice guidelines, also may include clinic/hospital administrators, service line directors, and other

	staff involved in the clinic/hospital's device procurement process.
RCA	Root Cause Analysis
SME	Subject Matter Expert
TAP	Total Product Lifecycle Advisory Program
TAP Advisor	An FDA employee who coordinates proactive and strategic engagement between FDA, Innovators, and non-FDA parties. Their expertise and guidance help participants navigate the program effectively and contributes to key outcomes like faster review timelines and stronger strategic planning.
TPLC	Total Product Lifecycle
VA	Department of Veteran Affairs
VC	Venture Capitalist

1.2 Customer Satisfaction Surveys Methodology and Data Collection

Approach: An online survey was administered to capture TAP Pilot participant feedback and satisfaction across all participants and maintain confidentiality.

Scope: To capture data over time with Pilot expansion, the CSAT survey utilized in this assessment captures data across 2 waves. Wave 1 was conducted between September 2024 to November 2024 and captured feedback from all TAP Pilot participants. Wave 2 was conducted from June 2025 to July 2025 and captured feedback from all participants that were in the TAP Pilot, including resurveying those from Wave 1.

Objective: To gather satisfaction data and experiences from TAP Pilot participants (Innovators and non-FDA parties) around their interaction and engagement experience in the TAP Pilot.

Topics: The CSAT survey covered the following topics listed below.

Table 4: Topics and Details of the Customer Satisfaction Surveys

Topic	Details
Participant Demographics	Organization Type; Number of interactions in last 6 months
Participant Satisfaction	Likert scale feedback on quality/efficiency/timeliness
Quality of Strategic Decision-Making	Likert scale on the effectiveness of TAP Pilot interaction on organization's strategic decision making; agree or disagree if you have the regulatory requirements to get device approved to market
Time Commitment to TAP Pilot	Number of hours invested in TAP Pilot Participation (past 6 months)
Level of Collaboration	Agree or disagree: Overall, TAP interactions with FDA and external stakeholders were highly collaborative.
Quality of Training and Support Materials	Likert scale measuring helpfulness of Kickoff/Orientation Materials, Email exchanges, TAP webpage
Quality of Sponsor Device Marketing Application	Likert scale rating confidence in device gaining market approval from the FDA on the first cycle.
Efficiency of Premarket Review Process	Likert scale rating confidence in device gaining market approval from the FDA on the first cycle.

Expectations Regarding Evidence Generation	Agree or disagree: better understanding of expectations regarding evidence generation because of my participation in the TAP Pilot.

***Description of Data Collection**:* The Customer Satisfaction (CSAT) Survey was conducted using SurveyMonkey, an online survey platform, allowing participants to provide feedback in a confidential setting. The survey was designed using a combination of Likert scale questions, open-ended responses, and multiple choice with logic to avoid irrelevant questions. The CSAT Survey invitations were sent via email to all TAP Pilot participants (Innovators and non-FDA parties). For Wave 1, the survey was open for 6 weeks. For wave 2, the survey was open for three weeks. Both waves included multiple reminders sent to ensure appropriate time to provide feedback.

Respondent Pool: Wave 1 of the Innovator CSAT survey had a response rate of 86%, with 42 of 49 total participants completing the survey. Wave 1 of the non-FDA party CSAT survey had a response rate of 71%, with 12 of 17 total participants completing the survey. Wave 2 of the Innovator CSAT survey had a response rate of 79%, with 63 of 80 total participants completing the survey. Wave 2 of the non-FDA party CSAT survey had a response rate of 49%, with 31 of 63 total participants completing the survey.

1.3 Participant Interviews Methodology and Data Collection

Approach: Participant Interviews were conducted to help clarify qualitative survey data and gather more details on the value and improvement opportunities of the TAP Pilot.

Scope: To capture data over time with Pilot expansion, the interviews were conducted across 2 waves. Wave 1 was conducted from October 2024 to January 2025. Wave 2 was conducted from June 2025 to August 2025.

Objective: Participant Interviews were conducted to help clarify qualitative survey data and gather more details on the value and improvement opportunities of the TAP Pilot.

Topics: The interviews covered the following topics outlined below.

Table 5: Topics and Details of the Participant Interviews

Topic	Questions (non-exhaustive)
Participant Demographics	Which type of interaction did you use most frequently? Why?
Participant Satisfaction	What could the FDA do differently, if anything, to make your interactions more valuable?
Quality of Strategic Decision-Making	How did your participation in the TAP Pilot affect your organization's… • understanding of risk management? • understanding of FDA regulatory requirements for marketing approval? • understanding of commercialization / payer reimbursement?
Time Commitment to TAP Pilot	Tell us more about your time commitment to the TAP Pilot. Did your invested time change or remain the same throughout the Pilot?

Level of Collaboration	Please describe how you collaborated among stakeholders in these interactions?
Quality of Training and Support Materials	As you enrolled in the Pilot, how helpful did you find the orientation and materials?
Quality of Sponsor Device Marketing Application	Tell us more about the expected future of your device. How did your participation in the TAP Pilot impact your next steps of your device development plan?

***Description of Data Collection**:* During each wave of data collection, up to 30 interviews were conducted across Innovators and non-FDA parties. Interviewees were selected to ensure an equal mix across time in Pilot, device type, and number of interactions.

Respondent Pool: Wave 1 consisted of 29 interviews conducted. Wave 2 consisted of 25 interviews conducted.

1.4 Participant Observations Methodology and Data Collection

Approach: Observation of TAP Pilot interactions allowed to capture supporting data for this assessment.

Scope: Observations were conducted from September 2024 to August 2025 of interactions between Innovators and FDA staff. Interactions were observed via Microsoft Teams.

Objective: Interactions were observed to gauge topics such as level of engagement with the TAP Pilot, level of collaboration, and quality of interactions.

Topics: The meetings observed covered the following topics outlined below.

Table 6: Topics and Details of the Participant Observations

Topic	Questions (non-exhaustive)
Level of Engagement with TAP Pilot	Do all intended participants join the meeting? Do meeting participants introduce themselves when relevant? Are the goals or objectives of the meeting outlined from the beginning of the teleconference?
Level of Collaboration	Are all team members engaged and participating? • Do all team members participate? • Do team members ask questions? • How was feedback provided and received? • Did participants feel comfortable engaging in the discussion?
Program and Submission Activities and their Timeliness	Did the teleconference start on time? Did the teleconference end with clear, next steps outlined?
Quantity and Quality of Teleconference and Interaction Feedback	Do people suggest options or opinions that may differ from those around them? Was the meeting documented with minutes?

Description of Data Collection: We attended and passively observed formal teleconferences and informal interactions in the TAP Pilot and subsequently completed standardized observation forms to collect data. TAP Pilot participants received emails in advance notifying them of the intention to observe their meeting. Participants had 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.

Respondent Pool: We implemented 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. Our sample size estimate of 100 was calculated based on strata including OHT, organization size, engagement level, and type of teleconference. The plan was to observe two meetings from each unique combination of strata. 82 participant observations were completed.

1.5 Participant Pulse Surveys Methodology and Data Collection

Approach: Capturing pulse survey data allowed for point-in-time data to track trends over time, as well as interaction-specific data.

Scope: Pulse surveys capture participant satisfaction data for each formal regulatory interaction.

Objective: Interaction level pulse surveys help capture trends over time, or by types of interactions in the TAP Pilot. It also provides Innovators or Non-FDA parties with the ability to provide feedback for improvement opportunities.

Topics: The pulse surveys covered the following topics outlined below.

Table 7: Topics and Details of the Participant Pulse Surveys

Topic	Questions (exhaustive)
Participant Satisfaction	Please rate your overall satisfaction of this interaction on a scale of 1-10, 1 being extremely dissatisfied, 10 being extremely satisfied.
Participant Satisfaction	Please provide any other comments or feedback below.

Description of Data Collection: We sent pulse surveys to TAP Pilot participants via email within 3 business days of completed formal interactions in the TAP Pilot. The pulse survey link remained 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.

Respondent Pool: We used a systematic sampling method for pulse surveys, sending 1 after every 3 interactions by type of interaction (e.g., teleconference, written feedback) and device type, with a total sample size of 96 pulse surveys administered. This sampling method allows for sufficient accuracy in estimating satisfaction with interactions while also reducing burden on respondents and FDA. 34 pulse surveys were completed.

1.6 CDRH Administrative Records Methodology and Data Collection

Approach: Administrative data review was required for reporting on MDUFA V metrics, but also served as supporting data for interaction metrics, progress implementing the TAP Pilot, and improvement opportunities.

Scope: Program level documentation and administrative records measures timely adherence to process as well as provides insights into trends.

Objective: This assessment utilizes administrative data within CDRH databases to measure process metrics.

Description of Data Collection: Data from January 2023 to August 2025 were reviewed to examine metrics on completed amendments by type, adherence to MDUFA metrics, enrollment trends, interaction topics, and key questions, comments, and feedback captured through emails.

Data Sources: The data sources investigated are outlined below.

Table 8: Systems and Descriptions of the CDRH Administrative Data Collection

System	Description
Center Ad Hoc Reporting System (CARS)	Backend database used to extract CTS tables and reports using Business Objects.
Center Tracking System (CTS)	Internal FDA platform used to track Innovator-level submission data, including enrollment data, amendments, and device-related classifications.
Internal TAP Inbox (TPLC-Advisory-Program@fda.hhs.gov)	Outlook inbox used to filter enrollment requests from Innovators and non-FDA parties, routine amendment and interaction requests, and general comments, questions, and concerns related to the TAP Pilot.
Smartsheet Interaction and Amendment Data	Internal FDA document logging Innovator-level interaction summary, date, topic, and participating parties.

1.7 Evaluation Questions

A comprehensive list of all evaluation questions considered has been itemized below.

- To what extent is TAP achieving its intended outcomes (short, mid, long)?
- To what extent are TAP Pilot participants satisfied with the timeliness, frequency, quality, and efficiency of interactions with and written feedback from FDA?
- To what extent are TAP Pilot participants satisfied with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized)?
- How does TAP Pilot participant satisfaction with FDA-facilitated interactions compare to TAP Pilot participant satisfaction with non-FDA facilitated stakeholder interactions?
- To what extent are TAP Pilot participants and other stakeholders satisfied with their experience throughout the device development and review process?

- To what extent does the TAP Pilot contribute to improved strategic decision-making during the device development process, including earlier identification, assessment, and mitigation of product-development risk?
- To what extent are device marketing submissions of TAP Pilot participants high quality?
- What effect does TAP have on the efficiency of the premarket review process?
- Do TAP Pilot participants experience less time from granting of Breakthrough designation to receipt of marketing submission?
- Do TAP Pilot participants experience less time from receipt of marketing submission to marketing authorization?
- Do TAP Pilot participants experience fewer requests for additional information during submission review?
- To what extent is TAP responsible for achieving intended outcomes (i.e., do participants have improved outcomes as a result of TAP)?
- Do outcomes (e.g., sponsor satisfaction with FDA interactions) differ based on different program participants?
- To what extent do outcomes differ across Pilot participants based on how much they interacted with TAP?
- To what extent do outcomes differ between TAP Pilot participants and non-participants?
- To what extent do outcomes differ based on inputs (e.g., review team members, management, etc.)?
- To what extent do outcomes differ between TAP Pilot participants with different levels of Breakthrough Device Program experience?
- How does Pilot participant satisfaction with FDA-facilitated interactions compare to Pilot participant satisfaction with non-FDA facilitated stakeholder interactions?
- To what extent is TAP being implemented as intended?
- What progress has been made in implementing TAP?
- To what extent are TAP resources allocated efficiently/effectively?
- To what extent are there any challenges with managing/implementing TAP?
- To what extent is TAP meeting its MDUFA V commitments?
- To what extent is TAP meeting enrollment goals for each FY?
- What resources would be required to scale up the TAP Pilot to full implementation?

1.8 Root Cause Analysis

Root Cause Analysis is a structured process used to identify the underlying factors that contribute to an issue, rather than addressing only its surface-level symptoms. The goal is to understand why issues occur and to prevent their recurrence through targeted corrective and preventive actions.

Methodology: A collaborative approach was used to analyze the key pain points identified during the assessment. The team employed tools such as Microsoft Whiteboard to map issues visually and applied a “5 Whys” analysis to uncover their fundamental causes.

Through this process**, two key root causes** were identified, forming the foundation for the pain points, improvement opportunities, and recommended actions outlined in this report.

Key Root Causes Identified:

- ***Rapid Launch and Expansion of the TAP Pilot:*** As a first-of-its-kind program, the TAP Pilot has grown rapidly, requiring staff and processes to adapt quickly as it enrolled more Innovators and expanded to additional device areas.

- ***Resource Constraints / Workload Management:*** While new review staff were added, TAP's operations reflected its status as a Pilot program in a resource-limited FDA environment, with capacity and processes evolving alongside implementation.

1.9 Additional TAP Participant Case Studies

The following case studies draw on feedback from interviews and surveys with innovators, supplemented by observations gathered throughout the assessment.

TAP Pilot Enables Medical Device Company to Secure Funding

SITUATION: A medical device company was unclear whether their device would require a De Novo versus 510(k) pathway and needed funding for their pilot study but there were perceived regulatory risks.
ACTION: Through the TAP Pilot, the company received specific guidance confirming their 510(k) pathway through informal conversations with FDA reviewers. They strategically leveraged their TAP participation as a key differentiator in funding discussions to demonstrate a de-risked regulatory pathway.
IMPACT: The company successfully secured funding for their pilot study. The TAP Pilot participation dramatically improved regulatory clarity and reduced the likelihood of costly errors.

Figure 24: Case study detailing an Innovator that successfully secured funding by achieving increased regulatory clarity as a result of TAP Pilot participation.

TAP Pilot Provides Valuable Insights that Potentially Saved 2 Years of Device Development Time

SITUATION: An Innovator needed new CPT codes for physician billing. FDA reimbursement experts discussed withdrawing their CPT application, suggesting it was too early and likely to face rejection.
ACTION: Through seven months of TAP discussions and breakthrough designation interactions, the company engaged in strategic conversations with FDA about their commercialization approach and regulatory pathway.
IMPACT: The company made a fundamental strategic pivot, deciding not to commercialize their first product but instead conduct an IDE study to set up for a pivotal trial with their implantable product. This decision potentially saved two years of development time.

Figure 25: Case study detailing an Innovator that estimated saving two years of development time due to strategic commercialization conversations through the TAP Pilot.

TAP Pilot Accelerates Clinical Development Through Amendment Process

SITUATION: An Innovator had a platform technology for one diagnosis that they wanted to apply to a different diagnosis. They needed FDA guidance on clinical study design for this new indication but faced potential delays through traditional Q-submission processes.
ACTION: The company submitted TAP amendments for clinical study feedback and leveraged the faster 40-day turnaround times instead of traditional 70-day Q-submission timelines. They also engaged with FDA reviewers through monthly touch-base calls to plan submissions strategically.
IMPACT: The TAP amendment process provided faster feedback (40-day vs traditional Q-sub timelines) that was incorporated into their IDE submission. The sponsor achieved first-round IDE approval, though multiple factors may have contributed to this outcome.

Figure 26: Case study in which the amendment structure of the TAP Pilot enabled an Innovator to achieve first-round IDE approval.

1.9 Additional TAP Participant Case Studies (continued)

TAP Pilot Accelerates Regulatory Submission by 12+ Months Through Strategic Study Redesign

SITUATION: A company was seeking guidance around study design, as they initially planned to conduct a prospective study for their medical device.
ACTION: During informal interactions with FDA, they engaged in open dialogue to understand the requirements and feasibility of prospective studies and retrospective studies.
IMPACT: By changing the clinical strategy based on FDA advice, the company was able to significantly accelerate their timeline for FDA submission. This strategic shift, facilitated by TAP Pilot participation, potentially saved them over a year in their development process. Therefore, the TAP Pilot's collaborative approach allowed the company to explore alternative strategies, leading to a potentially significant time savings in their product development and regulatory submission process.

Figure 27: Case study detailing an Innovator that accelerated their FDA submission timeline by over 12 months through strategic study redesign enabled by TAP Pilot participation.

TAP Pilot Delivers Biocompatibility Risk Assessment Feedback to Help Avoid Future Testing Costs

SITUATION: An Innovator was developing an implant with two device versions requiring complex biocompatibility testing. The company needed FDA guidance on which tests were necessary to avoid costly mistakes and regulatory delays.
ACTION: Through TAP's monthly touch-base meetings and formal written feedback process, the company submitted a comprehensive biocompatibility risk assessment and gap analysis document (25+ pages) after several preparatory discussions with FDA reviewers.
IMPACT: The company received detailed written feedback on their biocompatibility risk assessment that they anticipated would help guide future testing decisions and avoid costly mistakes, though implementation had not yet occurred at the time of interview.

Figure 28: Case study showing how an Innovator used TAP Pilot participation to obtain FDA feedback on a biocompatibility risk assessment, helping guide future testing decisions and reduce potential costs.

TAP Pilot Helps Sponsor Avoid Unnecessary Testing Requirements

SITUATION: An Innovator was developing a high-risk device and was uncertain about extensive fatigue testing and element analysis requirements that could delay their clinical investigation by months and cost significant resources.
ACTION: The company consulted with FDA through TAP meetings about their testing protocol and received guidance on which tests were actually necessary for their clinical investigation stage.
IMPACT: FDA advised that fatigue testing was not required during the clinical investigation stage, saving the company 5 months of preparation time and substantial equipment costs.

Figure 29: Case study highlighting how an Innovator leveraged TAP Pilot participation to clarify testing requirements, avoiding unnecessary fatigue testing and saving significant time and resources.

1.9 Additional TAP Participant Case Studies (continued)

TAP Pilot Accelerates Sponsor's Understanding of FDA and Approval Process, Saving Over 1 Year

SITUATION: An Innovator had been struggling with FDA interactions for two years on their device. Despite having breakthrough designation, their Q-sub process was slow, and responses were unclear, creating a "rolling ball that never got anywhere."
ACTION: Through TAP, they engaged in bi-weekly interactions with their review team, submitted multiple amendments for specific questions, and received direct feedback on protocol design and regulatory strategy. They broke down their complex indication into smaller, more manageable submissions.
IMPACT: The company accelerated their timeline by approximately one year, submitted multiple 510(k) applications that are nearing approval, and fundamentally changed their understanding of FDA requirements and approval strategy.

Figure 30: Case study showing how an Innovator accelerated FDA approval by over a year through TAP Pilot participation, gaining clearer guidance on study design and regulatory strategy.

TAP Pilot Accelerates Regulatory Strategy Development for Novel Technology

SITUATION: A company received breakthrough designation but faced uncertainty about regulatory pathways for their novel AI-driven device.
ACTION: The company submitted written feedback requests to TAP for their non-clinical and clinical plans for their early feasibility study, engaged in monthly informal discussions with their TAP advisor, and participated in topic-specific meetings to clarify FDA expectations for their novel technology area.
IMPACT: TAP provided significantly faster regulatory guidance compared to traditional Q-Sub processes, enabling the company to move forward with greater clarity and confidence. The informal access allowed for nuanced discussions about their complex technology that wouldn't have been possible through formal channels.

Figure 31: Case study showing how an Innovator accelerated regulatory strategy development for a novel device through TAP Pilot participation, gaining faster guidance and clearer expectations.

TAP Pilot Facilitates Crucial Industry Connections and Enhances Visibility for Medical Device

SITUATION: A company was struggling to engage with external parties, particularly lower-tier hospitals, that would be the primary users of their device. They lacked the necessary introductions and were concerned about getting sufficient design input from potential end-users.
ACTION: Through the TAP Pilot, the FDA facilitated introductions to patient advocacy groups and relevant healthcare institutions. The company leveraged the FDA's established relationships to initiate these connections.
IMPACT: The FDA-backed introductions led to increased attention and engagement from target organizations. The company gained access to potential end-users, allowing them to gather more comprehensive design inputs. Additionally, they were offered the opportunity to publish a paper about their device in a newsletter distributed, enhancing their visibility in the field.

Figure 32: Case study showing how an Innovator leveraged TAP Pilot participation to build key industry connections, gain end-user input, and increase visibility for their devices

1.9 Additional TAP Participant Case Studies (continued)

TAP Pilot Enables Early Reimbursement Strategy and CPT Code Development

SITUATION: A small startup sponsor had limited business development resources and was primarily focused on technical product development without considering reimbursement strategy.
ACTION: TAP provided visibility into the CPT code process, connected them with professional societies, and helped them participate in CPT code discussions for their space, allowing them to provide input on broad code development even when competitors had already initiated the process.
IMPACT: The company gained early involvement in reimbursement processes that would typically occur post-approval, potentially saving significant time and money by addressing business considerations parallel to regulatory approval rather than sequentially.

Figure 33: Case study showing how an Innovator used TAP Pilot participation to engage early in reimbursement strategy and CPT code development, saving time and resources.

TAP Pilot Strengthens Stakeholder Engagement and Builds Key Industry Relationships

SITUATION: A company was developing their device and needed to understand how their innovative technology would be received by professional societies and ensure their device design would be accepted by the applicable healthcare community.
ACTION: Through TAP, the company engaged with healthcare association representatives to understand guidelines, acceptance criteria, and design preferences. They also connected with reimbursement specialists they had previously identified as too expensive to hire directly.
IMPACT: The company received validation that their technology was "revolutionary" and would "change the way people think or treat," along with specific recommendations for ease of use. This feedback was integrated into their design inputs.

Figure 34: Case study highlighting how an Innovator leveraged TAP Pilot participation to strengthen stakeholder engagement, gain healthcare community feedback, and build key industry relationships.

Startup Refocuses Value Proposition Through Patient and Stakeholder Engagement

SITUATION: A medical device company had lost focus on patient benefits after years of development, becoming overly concentrated on technical specifications and regulatory approval rather than real-world healthcare value.
ACTION: Through TAP's stakeholder engagement component, the company participated in discussions with patient societies, physician groups, and healthcare stakeholders facilitated by FDA connections. These interactions provided high-level strategic discussions about the broader healthcare impact of their technology.
IMPACT: The company developed a "very, very clean value proposition" that was more precise and patient-focused than their original approach. They gained crucial insights into what would make healthcare better for patients and families, refocusing their marketing strategy on meaningful outcomes rather than technical metrics.

Figure 35: Case study illustrating how an Innovator used TAP Pilot participation to refine their value proposition through patient and stakeholder engagement, shifting focus toward meaningful healthcare outcomes.

1.9 Additional TAP Participant Case Studies (continued)

TAP Pilot Saves Medical Device Company a Significant Sum Through Strategic De-risking

SITUATION: A medical device company enrolled in TAP, initially believing they had a clear regulatory pathway but lacked comprehensive understanding of market adoption challenges and the broader commercial landscape.
ACTION: The TAP team connected the company with experts across multiple domains including marketing, supply chain, hospital administration, and reimbursement specialists. Through monthly check-ins and facilitated meetings, TAP provided a holistic view of the total product lifecycle beyond just regulatory approval.
IMPACT: TAP helped the company identify and mitigate significant business risks that could have led to costly failures in clinical studies and market adoption. By providing strategic insights into market dynamics and stakeholder perspectives, TAP enabled the company to build a more informed and lower-risk development path.

Figure 36: Case study demonstrating how an Innovator leveraged TAP Pilot participation to de-risk their development strategy, avoiding potential pitfalls and saving a significant sum of money.

TAP Pilot Accelerates Development Timeline and Strategic Planning Saving Company Years of Time

SITUATION: A medical device company enrolled in TAP needed to navigate evolving FDA guidance for their innovative technology, while finding an efficient development strategy given limited resources.
ACTION: TAP supported the company in implementing parallel processes for regulatory and non-regulatory strategies. The company leveraged collaborative interactions with FDA and gained early insights into reimbursement pathways to refine their overall strategic approach.
IMPACT: Interactions and knowledge gained through TAP resulted in more strategic resource allocation, such as the hiring of regulatory staff and consultants earlier in the development process. TAP also provided early discussion on reimbursement requirements, ultimately saving the company years in development time.

Figure 37: Case study highlighting how an Innovator used TAP Pilot participation to streamline strategic planning and parallel processes, saving years in development time.

1.10 Assumptions

Assumptions stated are to provide transparency around the foundational premises underlying the assessment's methodology, conclusions, and improvement opportunities. The assumptions are as follows:

- Innovators will take written and verbal feedback into account when making updates to development plans and/or submissions
- Interactions with FDA increase the quality of submissions and plans
- Higher quality submissions will expedite the premarket review process
- Successful experiences will cause more Innovators to participate in the Pilot
- Innovators will continue to voluntarily enroll in the TAP Pilot each FY
- Non-FDA parties will continue to voluntarily engage with the TAP Pilot
- Both FDA and Innovators will follow process and timeline requirements

1.11 Limitations and External Factors

Limitations and external factors refer to the real-world constraints of the assessment. These considerations help identify potential risks that could affect the scope or outcomes of the assessment. Limitations are as follows:

- ***Availability of CDRH staff and resource teams:*** Limited staff availability can delay review timelines and reduce the depth of technical analysis
- ***Economic/market conditions:*** Fluctuating economic conditions can impact industry resources and influence the feasibility of implementing recommended activities for opportunities for improvement.
- ***Public health conditions:*** Evolving public health emergencies or conditions may shift regulatory priorities
- ***Administration priority changes:*** Evolving administration priorities may impact staffing levels and available expertise

1.12 Participant Survey Questions

This appendix includes the survey questions utilized to inform the assessment. The questions are organized by audience type and were used across both waves of data collection.

Innovator Survey Questions: Wave 1 and Wave 2

1. What position or role do you hold within your organization?
   Answers: Multiple choice
2. What size is your organization?
   Answers: Multiple choice
3. How long has your organization been operating in the medical device space?
   Answers: Multiple choice
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?
Answers: Multiple choice

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?
   Answers: Multiple choice
6. Did your organization engage in formal teleconferences with FDA (teleconferences that require formal amendment submission) during the TAP Pilot period?
   Answers: Yes/No
7. Formal teleconferences with FDA are those that require formal amendment submission. How satisfied or dissatisfied was your organization with each of the following aspects of formal teleconferences with FDA?
   Answers: 5-point Likert scale from very satisfied to very dissatisfied
8. Were your formal teleconferences with FDA too frequent, too seldom, or just about right?
   Answers: Multiple choice
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?
   Answers: Yes/No
10. Informal check-ins with FDA are routine or ad-hoc touch-bases that are not documented as a TAP amendment. How satisfied or dissatisfied was your organization with each of the following aspects of informal check-ins with FDA?
    Answers: 5-point Likert scale from very satisfied to very dissatisfied
11. Were your informal check-ins with FDA too frequent, too seldom, or just about right?
    Answers: Multiple choice
12. Did your organization engage in written feedback from FDA on biocompatibility and sterility topics during the TAP Pilot period?
    Answers: Yes/No
13. Written feedback from FDA on biocompatibility and sterility topics are those requests that require an amendment submission. How satisfied or dissatisfied was your organization with each of the following aspects of written feedback from FDA on biocompatibility and sterility topics?
    Answers: 5-point Likert scale from very satisfied to very dissatisfied
14. Was your written feedback from FDA on biocompatibility and sterility topics too frequent, too seldom, or just about right?
    Answers: Multiple choice
15. Did your organization engage in written feedback from FDA on other NON-biocompatibility and sterility topics during the TAP Pilot period?
    Answers: Yes/No
16. Written feedback from FDA on other non-biocompatibility and sterility topics are those requests that require an amendment submission. 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?
    Answers: 5-point Likert scale from very satisfied to very dissatisfied

17. Was your written feedback from FDA on other NON-biocompatibility and sterility topics too frequent, too seldom, or just about right?
    Answers: Multiple choice
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.
    Answers: Yes/No
19. Did your organization engage in voluntary interactions with non-FDA payer consultants/subject matter expects (SMEs) facilitated by FDA? Payer consultants/subject matter experts (SMEs): Individuals that advise on payment or services rendered by a healthcare provider.
    Answers: Yes/No
20. What is the primary reason for NOT interacting with non-FDA payer consultants/subject matter experts (SMEs) through the TAP Pilot?
    Answers: Multiple choice
21. Payer consultants/SMEs are individuals that advise on payment or services rendered by a healthcare provider. 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?
    Answers: 5-point Likert scale from very satisfied to very dissatisfied
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?
    Answers: Multiple choice
23. Did you 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.
    Answers: Yes/No
24. What is the primary reason for NOT interactions with non-FDA healthcare providers and professional societies through the TAP Pilot?
    Answers: Multiple choice
25. Healthcare providers and professional societies are individuals or groups that provide feedback on clinical evidence generation, reimbursement, and clinical practice/new technology adoption. 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?
    Answers: 5-point Likert scale from very satisfied to very dissatisfied
26. Were your voluntary interactions with non-FDA healthcare providers and professional societies facilitated by FDA too frequent, too seldom, or just about right?
    Answers: Multiple choice
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.
    Answers: Yes/No
28. What is the primary reason for NOT interacting with non-FDA patient organizations/subject matter experts (SMEs) through the TAP Pilot?
    Answers: Multiple choice

29. 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. 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?
    Answers: 5-point Likert scale from very satisfied to very dissatisfied
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?
    Answers: Multiple choice
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)?
    Answers: Yes/No
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?
    Answers: 5-point Likert scale from much better to much worse
33. Please explain what made interactions facilitated by FDA better or worse.
    Answers: Free-text field
34. What is the MOST significant action that you took as a result of what you learned through interactions with non-FDA stakeholders?
    Answers: Free-text field
35. Across all interaction types, which of the following topics did you cover in your interactions? Please select all that apply.
    Answers: Multiple select
36. How satisfied or dissatisfied was your organization with the feedback received on the topics identified?
    Answers: 5-point Likert scale from very satisfied to very dissatisfied
37. Overall, how satisfied or dissatisfied is your organization with its participation in the TAP Pilot?
    Answers: 5-point Likert scale from very satisfied to very dissatisfied
38. What were the primary drivers that influenced your response to the previous question?
    Answers: Free-text field
39. Which TAP Pilot interaction type do you prefer most?
    Answers: Multiple choice
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).
    Answers: Sliding scale from 0 to 10
41. The following questions ask about outcomes and impacts achieved from participating in the TAP Pilot as they relate to strategic decision-making. How much do you agree or disagree with the following statements:
    a. My organization has a better understanding of the regulatory requirements for getting our device approved by FDA as a result of participating in the TAP Pilot.
    b. My organization has become more knowledgeable about how to bring our medical device to market in the United States as a result of participating in the TAP Pilot.
    c. My organization has become more confident in our plan to bring or not to bring our medical device to market as a result of participating in the TAP Pilot.
    Answers: 5-point Likert scale from strongly agree to strongly disagree
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)?
    Answers: 5-point Likert scale from major positive effect to major negative effect

43. Has your organization realized benefits to your regulatory strategy as a result of your participation in the TAP Pilot?
    Answers: Yes/No
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.
    Answers: Multiple select
45. Has your organization realized benefits to your commercialization and patient access strategy as a result of your participation in the TAP Pilot?
    Answers: Yes/No
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.
    Answers: Multiple select
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?
    Answers: 5-point Likert scale from strongly agree to strongly disagree
48. The following questions ask about outcomes and impacts achieved from participating in the TAP Pilot as they relate to marketing applications. Does your organization expect to bring your device to market?
    Answers: Yes/No/Not Decided
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 marketing submission for your device for the proposed indications for use)?
    Answers: 5-point Likert scale from extremely confident to not at all confident
50. How much do you agree or disagree with the following statements?
    a. Participation in TAP is a value-add for our organization.
    b. FDA staff were highly collaborative throughout the TAP Pilot.
    c. External stakeholders were highly collaborative during TAP interactions.
    Answers: 5-point Likert scale from strongly agree to strongly disagree
51. 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?
    a. Kickoff/Orientation materials provided by FDA
    b. Email exchanges between your organization and FDA
    c. TAP webpage on fda.gov
    d. Meetings and phone calls with FDA staff
    Answers: 5-point Likert scale from very helpful to very unhelpful
52. Approximately how many employees at your organization are currently involved in the TAP Pilot? Enter answer as a whole number.
    Answers: Free-text field
53. Approximately how much total time (in hours) on average does a given employee spend participating in the TAP Pilot in a typical week?
    Answers: Multiple choice
54. What suggestions do you have for how FDA could make TAP interactions more valuable?
    Answers: Free-text field
55. Please provide any other comments or feedback for FDA.
    Answers: Free-text field
56. If you are willing to participate in a follow-up interview about the TAP Pilot, please provide your name and email address below.

Answers: Free-text field

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

Non-FDA Party Survey Questions: Wave 1 and Wave 2

1. Please select your organization type below.
   Answers: Multiple choice
2. What type of role do you hold within your organization?
   Answers: Multiple choice
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?
   Answers: Yes/No
4. How satisfied or dissatisfied was your organization with each of the following aspects of FDA-facilitated interactions with sponsors through the TAP Pilot?
   Answers: 5-point Likert scale from very satisfied to very dissatisfied
5. Were interactions too frequent, too seldom, or just about right?
   Answers: Multiple choice
6. How much do you agree or disagree with the following statement: TAP interactions with sponsors were highly collaborative.
   Answers: 5-point Likert scale from strongly agree to strongly disagree
7. How much do you agree or disagree that participating in TAP is a value-add for your organization?
   Answers: 5-point Likert scale from strongly agree to strongly disagree
8. In which of the following ways do you or your organization benefit from participation in the TAP Pilot? Please select all that apply.
   Answers: Multiple select
9. Approximately how many employees at your organization are currently involved in participating in the TAP Pilot? Enter answer as a whole number.
   Answers: Free-text field
10. Approximately how much total time (in hours) on average does a given employee spend participating in the TAP Pilot in a typical week?
    Answers: Multiple choice
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?
    a. Materials provided by FDA
    b. Email exchanges between your organization and FDA
    c. TAP webpage on fda.gov
    d. Meetings and phone calls with FDA staff
       Answers: 5-point Likert scale from very helpful to very unhelpful
12. What suggestions do you have for how FDA could make TAP interactions more valuable?
    Answers: Free-text field
13. Please provide any other comments or feedback for FDA.
    Answers: Free-text field
14. If you are willing to participate in a follow-up interview about the TAP Pilot, please provide your name and email address below.

Answers: Free-text field

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

1.13 Participant Interview Questions

This appendix includes the lists of interview questions utilized to inform the assessment. The questions are organized by audience type and were used across both waves of data collection.

Innovator Interview Questions: Wave 1 and Wave 2

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 impacts of TAP on your organization. How did your participation in the Pilot impact 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?

Non-FDA Parties Interview Questions- Wave 1 and Wave 2

1. We gather that you had *[Number and Type of Interactions]* with *[Sponsors].* Tell me more about those interactions.
    a. How did the facilitation through introductions made by FDA impact your experience with these sponsors?
    b. Please describe how you collaborated among sponsors in these interactions.
    c. What would you do differently, if anything, to make interactions more valuable?
    d. For interactions with sponsors introduced by FDA, what could the sponsor do differently, if anything, to make interactions more valuable?
    e. What could FDA do differently, if anything, to make interactions more valuable?
    f. As you began your participation in the TAP Pilot, how helpful did you find the orientation and supporting materials?
2. You *[agreed/disagreed]* in the survey that the TAP Pilot was a value-add. Why is that?
    a. Which aspects of the Pilot were particularly valuable to your organization? What factors contributed to an interaction being valuable? Can you give an example?
    b. Which aspects were less valuable?
3. 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?
4. We see in your survey results that you noted that participating in the TAP Pilot helped your organization achieve [*Relationship building with sponsors/Relationship building with FDA/Improved understanding of the pre-market medical device review process/Increased awareness of emerging technologies in medicine/Greater influence in the device development process/Other].* Could you elaborate on how the TAP Pilot helped you achieve this?
    a. What new information did the TAP Pilot provide your organization that helped you achieve this?
5. Would you recommend participating in the TAP Pilot to your colleagues? Why or why not?
6. If you had a magic wand, and could change anything about the TAP Pilot, what would you change? Why?
7. Is there any additional information you believe would be valuable for us to know?

1.14 Participant Observation Form

Teleconference Details

Date of Meeting	Click or tap to enter a date.
Meeting Start Time	Click or tap here to enter text.
Meeting End Time	Click or tap here to enter text.
Meeting Duration (in minutes)	Click or tap here to enter text.
Sponsor Name (i.e., company name)	Click or tap here to enter text.
Device Name	Click or tap here to enter text.
List of Other Organizations Present	Click or tap here to enter text.
List of Names, roles, and organization of meeting attendees	Click or tap here to enter text.
Observer Name	Click or tap here to enter text.
Amendment	☐ Yes (Amendment Number: Click or tap here to enter text.) ☐ No

Engagement with the TAP Pilot

Prompt	Answer	Observer Notes
Did all intended participants join the meeting?	☐ Yes ☐ No	Click or tap here to enter text.
Did participants introduce themselves when relevant?	☐ Yes ☐ No	Click or tap here to enter text.
Were the goals or objectives of the meeting outlined from the beginning of the meeting?	☐ Yes ☐ No ☐ N/A	Click or tap here to enter text.

Collaboration

Prompt	Answer	Observer Notes

Did all team members participate in the discussion?	☐ Yes ☐ No	Click or tap here to enter text.
Did team members ask questions?	☐ Yes ☐ No ☐ N/A	Click or tap here to enter text.
Did attendees suggest options or opinions that differed from those around them?	☐ Yes ☐ No	Click or tap here to enter text.
Did participants seem comfortable engaging in the discussion?	☐ Yes ☐ No	Click or tap here to enter text.

Quantity and Quality of Interaction

Prompt	Answer	Observer Notes
What type(s) of feedback were sought during the teleconference?	☐ General Strategy ☐ Commercialization ☐ Device Development Plan ☐ Regulatory Requirements ☐ Stakeholder Engagement Plan ☐ Other	Click or tap here to enter text.
Was the feedback provided by the team constructive and actionable?	☐ Yes ☐ No ☐ N/A	Click or tap here to enter text.
Were participants receptive to the feedback received?	☐ Yes ☐ No ☐ N/A	Click or tap here to enter text.
Were there agreements or resolutions reached during the teleconference?	☐ Yes ☐ No	Click or tap here to enter text.

Prompt	Answer	Observer Notes
	☐ N/A	

Program Submission Activities and Their Timeliness

Prompt	Answer	Observer Notes
Did the teleconference start on time?	☐ Yes ☐ No ☐ N/A	Click or tap here to enter text.
Did the teleconference end with clearly outlined next steps?	☐ Yes ☐ No ☐ N/A	Click or tap here to enter text.
Was the teleconference documented in minutes?	☐ Yes ☐ No ☐ N/A	Click or tap here to enter text.

1.15 Participant Pulse Survey Questions

1. On a scale from 0 to 10, please rate your satisfaction with this interaction. (0 for extremely dissatisfied, 10 for extremely satisfied)

2. Please provide any other comments or feedback below.