U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

TAP Pilot Engagement Tips

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Contents

Preamble

These tips draw on the U.S. Food and Drug Administration's (FDA) experiences engaging across the medical device ecosystem. They are intended to provide considerations that may foster effective engagement between medical device sponsors and non-FDA parties like patients, payers, and healthcare providers during the medical device design and development process.

The tips do not constitute Agency policy, guidance, recommendations, or directives. In addition, where references are cited herein, they are for informational purposes only and should not be construed as endorsements of their content.

These tips are developed for the Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot; however, the considerations for engaging non-FDA parties may be useful to device development generally. FDA involvement in engagements between TAP participants and non-FDA parties does not constitute an agreement or endorsement of the viewpoints of any non-FDA party by FDA or the Department of Health and Human Services (HHS). Engagement with non-FDA parties facilitated by the TAP Pilot does not change the regulatory pathway or the review process associated with a submission to FDA, nor does it replace or constitute a marketing submission. Ultimately, TAP participants must decide on their own strategies, evidence needs, and execution plans.

Terminology

Terminology used for purposes of this document includes the following:

TAP Pilot: Total Product Life Cycle (TPLC) Advisory Program Pilot

TAP participant: device developer who interacts with the FDA and non-FDA parties.

Non-FDA party: patients, healthcare providers, health insurers and other payers, and others who may have insights of interest to TAP participants and may engage in voluntary interactions with TAP participants.

Overview of TAP Pilot

The Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot is intended to help spur more rapid development of high-quality, safe, effective, and innovative medical devices that are critical to public health. TAP's primary goal is to expedite patient access to innovative medical devices by providing early, frequent, and strategic communications with the FDA and by facilitating engagement with other key parties for developers of devices of public health importance.

The TAP Pilot facilitates engagements with non-FDA parties (Figure 1) that can help TAP participants identify strategic options to streamline the path to market adoption and patient access to their devices. With the TAP Pilot, the FDA is striving to play a more active part in supporting patient access to innovative, safe and effective devices.

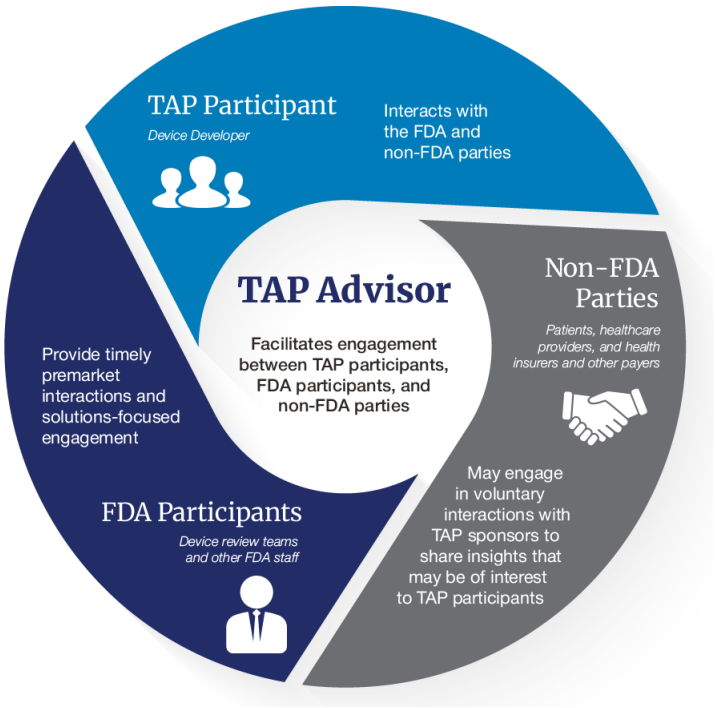

Figure 1. Parties involved in the TAP Pilot.

Engagement with Non-FDA Parties

As part of the TAP Pilot, a TAP participant may seek insights through early interactions with non-FDA parties. CDRH may facilitate interactions between TAP participants and non-FDA parties. Innovators may seek such engagements to inform key elements of their strategy including development of a novel medical product, incorporation into a clinical care paradigm, customer validation, evidence generation, market access, and product adoption.

Each non-FDA party has its own and perhaps a unique perspective that may help inform a sponsor at different stages of product development. A patient and a healthcare provider may provide different, but equally important, perspectives. For example, a patient may be able to share unmet needs in treating or managing a condition whereas a healthcare provider may be able to share how a new technology may or may not fit into the existing clinical care paradigm. Strategically planning when and how to engage with non-FDA parties can help sponsors receive timely insights that can inform business strategy and decision-making.

TAP participants may consider how these efforts could collectively address challenges to widespread adoption of their innovative device by better understanding patient needs, anticipating evidence needs for payers and healthcare providers, along with other market adoption considerations. In the TAP Pilot, non-FDA party engagement is intended to increase relevant information available to TAP participants. Input from non-FDA parties may have significant value in helping TAP participants increase efficiencies throughout a device's design development, during clinical trials, and planning for market adoption and patient access. Non-FDA party engagement can help TAP participants to streamline the path from concept to commercialization, toward the goal of ultimately increasing patient access to high-quality, safe, effective, and innovative medical devices.

Seeking Insights

TAP participants may consider seeking insights from parties in areas such as measuring outcomes that are important to patients and healthcare providers; publishing clinical investigation results; obtaining coding, coverage, and payment for their device; incorporating a device into professional guidelines; and/or achieving clinical adoption of their device. Depending on where a TAP participant is in the device development process (Figure 2), different insights may be desired.

Figure 2. General device development pathway. Early development activities may include, but are not limited to, discovery, ideation, invention, prototyping, and non-clinical testing. Clinical investigation activities may include, but are not limited to, planning, conduct, and analysis.

Insights sought during early-stage development when ideation and prototyping are main activities may differ compared to insights sought to support clinical trial design or evidence generation and adoption. The following tables list some potential topics when seeking insights from patients (Table 1), healthcare providers (Table 2), and payers (Table 3).

Table 1. Potential topics for patient insight throughout the device development pathway.

Patients		
Early Development	Clinical Investigation	Market Access & Adoption
• Challenges experienced in management and/or treatment of a disease or condition • Aspects of a disease or condition that are not addressed with existing therapies • Benefits and drawbacks of current treatment options • Desired product features and design elements • Barriers to patient acceptability • Inclusive human-centered design features	• Endpoints and benefits important to patients • Meaningful changes in patient function, symptoms, and quality of life • Patient views on acceptable benefit-risk tradeoff • Barriers to enrollment, participation, treatment adherence, and follow-up • Strategies for diverse recruitment and enrollment	• Patient burden of disease and limitations of current treatment options • Benefit-risk profile considered reasonable by patients with the condition • Quantitative studies about patient experiences and perspectives that inform other decision factors for market access and adoption

Table 2. Potential topics for healthcare provider insight throughout the device development pathway.

Healthcare Providers		
Early Development	Clinical Investigation	Market Access & Adoption
• Considerations for incorporation of a new device and/or procedure into a clinical workflow • Collaboration with professional societies, if applicable based on the technology and medical specialty involved with device use • Current standard of care for management and/or treatment of a disease or condition • Aspects of a disease or condition that are not addressed with existing therapies • Benefits and drawbacks of current treatment options	• Clinical study design, outcomes, and endpoints important to healthcare providers • Publication strategy and recommended journals • Barriers to subject enrollment, participation, treatment adherence, and follow-up • Strategies for diverse recruitment and enrollment	• Level of evidence needed to garner support from a professional society or payer, including considerations such as the study size, patient disease state, time for follow-up, etc. • Evidence portfolio, including evidence to show widespread adoption, needed to receive a Current Procedural Terminology (CPT®) code from the American Medical Association (AMA) • Insights into medical professional society practice guidelines, how a device or procedure is incorporated into guidelines, and what training is needed to integrate into practice • Registry data considerations and participation

Table 3. Potential topics for payer insight throughout the device development pathway.

Payers		
Early Development	Clinical Investigation	Market Access & Adoption
• Value proposition	• Clinical investigation considerations, including study design and outcomes and/or endpoints important to payers, as well as adequate inclusion of patient populations relevant to coverage decisions • Indications for use that are relevant to payers and beneficial to achieving commercialization and patient access	• Strategic evidence generation to support coding, coverage, and payment • Payment establishment planning

Planning for Effective Engagement

There are many ways of engaging depending on a TAP participant's needs and interests. This section outlines considerations that TAP participants could consider in planning engagements with non-FDA parties to obtain key insights needed to inform a product development strategy.

Define Goals and Objectives

An initial step for TAP participants may be to proactively define the objectives for the non-FDA party engagement and to share how they may use the insights gained to inform their product development strategy. For example, TAP participants may be interested in using patient insights to inform their overall value proposition or to help design a clinical study that can reduce barriers to participation in the study.

Identify Specific Experience of Interest

Defined goals and objectives can help a TAP participant consider what patient population, lived experiences, expertise, or other perspectives they might wish to seek. Depending on the objectives, TAP participants may be interested in deep insights from a smaller number of individuals or general insights from a larger number of individuals.

Specify Topics, Questions, and Format

Focusing on specific topics and questions can help facilitate engagements that are more effective in eliciting key insights. For example, a TAP participant may consider different engagement mechanisms to best meet the specified objective(s). Potential mechanisms for engagement can include, but are not limited to, obtaining input through:

- One-on-one interviews of key opinion leaders or patients with deep personal history with the disease or condition of interest;
- Discussion via focus group(s);
- Market survey (written or oral);
- Inclusion of a representative from a specific group in the clinical investigation advisory group(s); and/or
- Advisory board comprised of non-FDA party (for example, patient advisory boards for clinical studies).

When determining which mechanism(s) to use, it is critical to consider whether the interaction is considered human subject research.[1] In some instances, patient insights may be gained without the need for a formal human subject research protocol. [2] However, in other instances where the planned engagement meets the definition of human subject research, TAP participants should ensure that applicable human subject research protocols are followed.

Set Expectations and Establish Trust

Another consideration relates to mutually setting clear expectations among participants while also creating an environment of trust and respect.[3] Input from a non-FDA party reflects that specific party's viewpoint; however, the TAP participant or other non-FDA parties may not agree with the perspective. If multiple non-FDA parties intend to participate in the same engagement, establishing an environment of trust and respect can help the parties better understand each other's expectations and work together to optimize meeting those expectations throughout the engagement and any subsequent interactions.

Another consideration is that non-FDA parties feel that their input is heard and valued even if it is not always integrated in the final approach taken by the TAP participant. Part of setting *a priori* expectations may include clarifying to non-FDA parties that the TAP participant may not be able to share information about the impact of their input at all or until much later in the device development process.

Prepare Parties

If a meeting is the selected engagement mechanism, TAP participants can consider various ways to facilitate an effective meeting, such as giving attendees adequate time to prepare. Meeting preparation may include agreeing upon the discussion agenda, logistics, and

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[1] Additional details regarding human subject research can be found in Definition of Human Subjects Research | grants.nih.gov

[2] Examples of interactions that would not be viewed as human subject research can be found in the guidance entitled *Patient Engagement in the Design and Conduct of Medical Device Clinical Studies:* Patient Engagement in the Design and Conduct of Medical Device Clinical Studies | FDA

[3] Huggett J. Why Collaborations Fail. Stanford Social Innovation Review. 4 Jun 2018. https://ssir.org/articles/entry/why_collaborations_fail#. Accessed 19 Aug 2022.

expectations following the meeting.[4] Distributing pre-meeting materials, when feasible, may provide an opportunity for non-FDA parties to solicit input from their membership base or feedback from invited participants who may be unable to join the discussion. These materials may reduce the need for didactic content and facilitate more interactive dialogue, allowing the TAP participant to better accomplish the meeting objectives.

Address Confidentiality and Conflicts of Interest

An important consideration is confidentiality expectations and general boundaries prior to a discussion and/or sharing materials. TAP participants may voluntarily elect to share certain confidential information during engagement with non-FDA parties if agreed upon by the TAP participant and the non-FDA party. An additional consideration is that some non-FDA parties may feel more comfortable sharing sensitive and/or confidential information when an appropriate confidentiality commitment is in place to prevent disclosure of the information they share during the discussion.

Disclosure of financial and non-financial conflicts of interest, including the potential appearance of conflicts of interest, is another topic for consideration. For example, a TAP participant may discuss such disclosures with non-FDA parties prior to engaging so they have transparent awareness of how those potential conflicts could influence the insights shared. Conflicts or the appearance of conflicts may include, for example:[5]

- Financial stake or association with competing company and/or idea;
- Leadership board memberships;
- Consulting contract(s); and/or
- Personal beliefs and/or convictions.

When considering how to manage actual and perceived conflicts of interest, TAP participants can consider the impact of the potential conflict on the input to determine if the individual's expertise and input may be more important than an actual or perceived conflict of interest.

FDA's Involvement

Consistent with legal requirements governing Federal Agency conduct, the following considerations describe FDA's involvement in engagements between a TAP participant and a non-FDA party.

TAP does not design, coordinate, convene, or run engagements between TAP participants and non-FDA parties. Instead, TAP facilitates a way for TAP participants to request early interactions with non-FDA parties so they may better understand the patient perspective in developing medical

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[4] Social Entrepreneurs, Inc. Building and Sustaining Effective Collaborations. Available at https://alliancefornevadanonprofits.com/wp-content/uploads/2011/09/Research-Brief-Building-and-Sustaining-Collaborations.pdf. Accessed 19 Aug 2022.

[5] See Institute of Medicine of the National Academies. Conflict of Interest in Medical Research, Education, and Practice. Editors Lo B and Field MJ. Washington, DC: The National Academies Press, 2009.

devices, healthcare provider needs for market adoption, and payer needs for coverage and reimbursement.

FDA may facilitate engagement between a TAP participant and non-FDA party when the TAP participant is in the TAP Pilot. Through the TAP Pilot, FDA helps prepare TAP participants and non-FDA parties for productive interactions. As part of subsequent TAP Pilot interactions, FDA is available to discuss any insights received with the TAP participant with the goal of helping to align expectations regarding evidence generation.

FDA does not direct engagements between non-FDA parties and a TAP participant. The TAP participant and/or the non-FDA party will be responsible for determining the agenda and scope of any engagement. FDA may, at the request of the TAP participant, attend non-FDA party engagements as an invited observer; FDA will not respond to specific submission questions during the engagement. If a real or perceived conflict of interest arises for FDA participants before or during the engagement, FDA participants will recuse themselves from the engagement.

In regard to Freedom of Information Act (FOIA) requests, any material sent to FDA, including pre-engagement and/or post-engagement material, would be subject to the same review and redactions as any other trade secret or confidential submission information submitted to the Agency.

TAP participants are responsible for any contractual agreement, including compensation, that a non-FDA party may seek in return for time spent on an engagement activity.

Conclusion

Engagement with non-FDA parties like patients, healthcare providers, and payers may help provide a better understanding of the current diagnostic, treatment, and management options for a given disease or condition; highlight health outcomes that are most important to patients, healthcare providers, and payers; and clarify the information needed to support adoption and coverage of the technology in clinical care and patients' daily lives should the product be authorized for marketing.

For those medical device developers interested in learning more about the TAP Pilot, additional details, including eligibility criteria and procedures for requesting enrollment, can be found on the website. For other parties in the medical device ecosystem, like patient organizations, healthcare professional societies, or health insurers or other payers interested in contributing to the TAP Pilot as a non-FDA party, please email TPLC-Advisory-Program@fda.hhs.gov.