Patient Engagement Collaborative Meeting Summary

March 20, 2019
FDA White Oak Campus
10903 New Hampshire Avenue, Silver Spring, Maryland

OBJECTIVES

- Define potential scope, contents, and format(s) of a how-to guide for patients and patient groups engaging with the FDA on topics related to medical product development and other regulatory discussions.

KEY TAKEAWAYS

Over the course of the meeting, PEC members discussed several key takeaways for further consideration:

- In order to connect with patients, the FDA will need to provide a welcoming and transparent environment.
- Although resources for patients currently exist on the FDA website, a clearer organizational structure is needed, and information should be presented at an eighth-grade reading level.
- The FDA could benefit from considering avenues of communication beyond the website to reach populations who may not have internet access.
- Utilization of different forms of media, such as videos and podcasts, will be important in reaching the widest audience possible.
- Some patients are eager to offer their input, but need more direction and structure for how to do so. This may include suggestions about what kind of information the FDA needs or what format the information should take to be most helpful to the FDA.
- Many patients do not know that engaging with the FDA is an option and need a baseline education about what the FDA does and why the organization is seeking patient input.

SESSION I: REVIEW MEMBER IDEAS FOR HOW-TO GUIDE

A Review of Existing FDA Resources

After a welcome by Andrea Furia-Helms of the FDA Patient Affairs Staff and Amy Abernethy, the new FDA Principal Deputy Commissioner, the PEC began its first session by exploring the ways patients can be engaged to communicate with the FDA. Existing resources on the FDA website allow users to navigate the FDA, share a disease experience, engage in medical product development, or comment on FDA regulations.

Although the FDA had defined these four categories in the context of the PEC meeting, several PEC members commented that the website organizational structure was unclear, forcing site visitors to click on each link to find the resources that pertained to their needs.

Another critique of the existing resources on the website was the challenging language—in order to be accessible to all patients, the members said, an eighth-grade reading level should be treated as "the gold standard." One member also mentioned that links in the "For Patients" section of the website often redirected to information for industry, introducing further confusion.

PEC members agreed that it would be valuable to have a user-friendly, better organized website for patients that included not only action items on how to engage with the FDA, but also information on why engaging with the FDA is important. One suggestion was a navigation tool to walk each user through opportunities to engage at each phase of the medical product development process, from preclinical research to safety monitoring after a product is approved.

Reviewing Challenges

The members also outlined other challenges they see in their patient communities.

Many patients are hesitant to contact the FDA directly and would prefer to speak with an advocate who can engage with the FDA on their behalf. Other patients do not understand that engaging with the FDA is an option or do not understand how becoming engaged would benefit them.

These challenges could be addressed in two ways—first, by enhancing the content on the website and transforming the "For Patients" section into a user-friendly set of resources, and second, by increasing awareness of the patient-centered content and implementing new strategies to drive traffic to the website.

Brainstorming Ideas for How-to Guide

The attendees brainstormed ideas both individually and in groups to address the challenges brought up in the collaborative's discussion. Each team then shared its top two priorities with the larger group.

The first team discussed the creation of an ambassador program, where trusted community members could be trained as FDA ambassadors and help other patients become accustomed to the new, more approachable FDA. Once a person became an ambassador, he or she could train other community members to become ambassadors at libraries, churches, or community meetings. The team's first idea dovetailed with its second idea, which was a toolkit that would use real patients' stories in the form of videos and vignettes to support the "Train the Trainer" approach.

The second team discussed that a focus on engagement channels beyond the website was critical, especially to reach individuals who might not have reliable internet access. The team mentioned TV advertising, as well as pamphlets that could be distributed to patients by both hospitals and industry. The second team also discussed the importance of a brand for any patient engagement initiative undertaken by the FDA that is separate from the overall FDA branding and centered on plain language and visual cohesion.

The third team discussed different forms of outreach that would give the FDA a presence in the patient's care journey, such as a pamphlet that details why patients' voices are important in the process of medical product development. The team also discussed creating video testimonials from patients who have successfully engaged with the FDA, as well as social media posts and sponsored ads that would target individuals searching for information about their condition or disease online. Engaging with health care providers directly could also be important in encouraging the providers to advise their patients on FDA involvement. For its second idea, the team focused on ways to maintain patients' involvement with the FDA over time. To do this, the FDA could improve its website and communication, making the information more accessible to different types of learners through various modes of communication such as infographics or podcasts.

The presentations spurred some discussion about what audience the initiatives should reach. Some members suggested that "everyone is a patient," meaning that every individual will be affected or have an affected family member at some point in their lives, while others felt the audience needed to be streamlined to only current patients so that the messaging could remain targeted and specific. The collaborative also discussed that patients exist on a spectrum of engagement—patient representatives are often comfortable engaging with the FDA, while other patients with less experience might feel less comfortable. The group discussed that the target audience may need narrowing; they also discussed the possibility of a navigational tool that showed next steps based on their level of familiarity with the FDA.

SESSION II: BREAKOUT DISCUSSIONS—DEFINE POTENTIAL WORK PRODUCTS

During the afternoon session, the three teams met to discuss their work products. Topics discussed will be detailed in notes about Session III, when the teams came together to report their progress.

SESSION III: REVIEW PROGRESS AND PLANS

Based on breakout group work, members discussed the following in-depth ideas for enhancing patient and patient-group engagement with FDA.

Patient Ambassador Program and "Train the Trainer" Toolkit

The first team presented their idea for a patient ambassador program, titled "FDA Community Ambassadors," to create a partnership between the FDA and the community.

The ambassadors program would help to reach more people through individuals they trust. The team representative said the intended impact of the program is as follows:

- To create streamlined, consistent messaging that enables easy communication between patient ambassadors and the community;
- To get patients involved in the medical product development process;
- To create a sustainable infrastructure of two-way information flow between the FDA and the community; and
- To learn more about clinical endpoints of at-risk and underrepresented populations.

The team also decided that the FDA Community Ambassadors should strive to answer questions such as:

- What does the FDA do?
- What does the FDA not do?
- How are drugs and other medical products made?
- Why does the FDA care about engaging with patients?

Culturally appropriate communication would be an important component of this program to effectively reach community members. Examples brought forth by the team included phone conferences, a newsletter, and communication through artists and musicians.

Once ambassadors are trained, they may train other individuals with a "Train the Trainer" program, either on an individual level or through large meetings.

The success of this initiative could be measured through feedback, either directly to the FDA or through information that flows back to the ambassadors from the community.

Outreach and Engagement Channels Beyond the Website

This team had several ideas for additional engagement channels, including TV; radio; print materials, such as pamphlets or posters in community gathering places; and digital assets, such as videos or social media toolkits that patient advocate groups could use on their social channels. One common theme that ran through most of the team's conversations was the concept of a "multiplier effect," or the most effective way to capitalize on existing resources to reach the maximum number of people. Examples of this range from communicating with the existing patient advocate audience on social media channels with social media toolkits, to bringing pamphlets or an FDA presence to large disease-specific conferences to reach wider patient audiences.

Many pieces of content could be shared via these engagement channels, including:

- What the FDA does and what it regulates;
- What the FDA does not do;
- Why the FDA needs and wants to work with patients; and
- How the FDA protects patients' safety (to address one of the main concerns of participating in a clinical trial).

The team representative said the intended impact behind additional engagement channels was three-fold:

- To disseminate more information and cast a wider net to gain a larger audience;
- To educate people about the role the FDA plays in their lives and motivate them to get involved; and
- To create a sustainable message centered on public health.

This impact could be measured by several metrics, such as increased traffic to the website or overall increased engagement and interaction with the FDA (e.g. higher number of phone calls, more pamphlet requests, etc.).

Another important concept for the team was to meet people where they are. The team emphasized that tactics and channels would need to vary based on geographic location and audience. For instance, posters in transit systems may work well for urban areas, but the FDA will need to find other avenues to reach patients in rural areas, such as churches or barber shops.

The messaging could include stories from real patients to help the audience connect, although the team agreed that experiences are translatable, meaning that the resources would not need to be re-invented for each specific disease type. The team also agreed that it is important to include caregivers in this messaging and encourage them to get involved with the FDA as well.

Discussion also focused around the importance of getting providers and industry involved in spreading this message to patients. They wondered whether it would be possible to embed FDA messaging into medical school education, licensing and professional education credits (i.e. - CEU/CE), or courses that teach best research practices.

Website Improvement

The third team focused on ideas to improve the "For Patients" section of the FDA website. The intended impact was to create an environment that is welcoming, engaging, and transparent. The team envisioned a website that was clear and easy to navigate, and that clearly stated how patients' information would be used, especially in situations when patients were asked to share their experiences with their disease.

The team emphasized the importance of different forms of media and the use of multimedia. They also brainstormed about content that could be included on the website, including:

- An introduction to the FDA and why patient engagement with the FDA is important, possibly in the form of a video;
- Calls to action, such as Learn, Act, and Engage;
- A table of opportunities for patients to engage with the FDA; and
- A tool that helps guide the patient through the FDA decision-making process.

Suggestions for visual organization included clearly defined buckets of information and expandable accordions for those users who want more information. Website responsiveness/format was also considered, as many patients would be accessing the website via a smartphone or tablet.

WRAP-UP AND NEXT STEPS

Members reflected on their second meeting and discussed structure and discussion topics for future meetings. The group conveyed a sense of excitement about the future of the collaborative.

Several members said they would prefer to have additional in-person meetings and less frequent phone meetings—with in-person meetings, they felt they accomplished more, got more out of it, and had time to reflect on and process topics introduced in the meeting.

The members also discussed that they would prefer not to elect co-chairs, as the group has been working well together and they do not want to see a change in dynamic. The members suggested that individuals could volunteer to help plan specific meetings and to take on an additional time commitment for specific projects on a rotating basis.

DISCLAIMER

The views expressed in this meeting summary represent the individual perspectives of the attendees and do not necessarily represent the official views of the FDA or CTTI or of any organization with which the attendees are affiliated.

MEETING AGENDA

9:15 am	Welcome and Background
9:45 am	Principal Deputy Commissioner's Remarks
10:10 am	Session I: Review Member Ideas for How-To Guide
11:45 am	Lunch
12:45 pm	Session II: Breakout Discussions – Define Potential Work Products
2:15 pm	Break
2:30 pm	Session III: Review Progress and Plans
3:30 pm	Wrap-up and Next Steps
4:00 pm	Adjourn