Vitiligo PFDD Meeting Frequently Asked Questions

1. When is the PFDD meeting on vitiligo and how can I register to participate?

The U.S. Food and Drug Administration (FDA) is hosting this virtual meeting on Monday, March 8 from 10:00 a.m. to 2:30 p.m. EST. Click here to register to participate.

2. What is a Patient-Focused Drug Development (PFDD) meeting?

A PFDD meeting is a way for the FDA, which is responsible to reviewing new medical treatments, to understand what it is like to live with a certain condition or to take existing treatments for that condition. Since 2012, the FDA has hosted more than 20 of these meetings to learn about different diseases and conditions. This year, they are hosting a virtual PFDD meeting on vitiligo.

3. How will this meeting impact the vitiligo community?

The intent of the PFDD movement is to ensure that the FDA understands the perspectives of patients condition and keeps those in mind when reviewing prospective treatments. We want and need the FDA to understand the experiences of people with vitiligo, including the limitations it places on daily activities of life, the social frustrations, and the emotional pain.

Simply put, we want FDA officials to experience a day in our lives and to walk away with an understanding of what we want to see in future treatments for vitiligo. This includes giving the FDA meaningful insights into the level of risks we would be willing to accept in exchange for potential benefits in treatments as well as what treatment outcomes matter most to us. This meeting provides a unique forum to help achieve this objective.

4. What is patient-focused drug development?
For many years, Congress and patient advocates have been demanding that patients have a greater voice in the FDA medical product review process. Until recently, patients were seen largely as end users and customers or as participants in clinical trials but were rarely viewed as equal partners in this work.

This paradigm is now shifting via patient-focused drug development or PFDD for short. Simply put, PFDD is a suite of laws and policies that provide opportunities for patients to play a more engaged role in the FDA review process. The vitiligo PFDD meeting is one example of PFDD.

5. What goes on during a PFDD meeting?

The FDA follows a specific model for PFDD meetings. Each meeting includes the following:

- Presentation from a medical expert about the disease or condition, including current treatment options.
- Panels of people who speak about their experiences living with the disease or condition as well as with treatments.
- Discussion sessions where members of the audience can talk about their experiences with the disease or condition.

- Live polling questions about disease symptoms and treatments that audience members can answer via their mobile device or computer.
- Brief open comment session where other audience members (other than people with the disease or condition) can share their thoughts.

6. Will I have an opportunity to speak at the meeting?

Yes! There are a couple ways you can make sure your voice is heard at the meeting. Meeting participants can respond to live polling questions and participate in a moderated discussion to tell the FDA about their experience with vitiligo. There will also be two panels of people with vitiligo: one about the health effects and daily impacts of the condition and one about panelists' experiences with vitiligo treatments. If you are interested in being a panelist, please write brief responses to the questions in the attached document and send them to PatientFocused@fda.hhs.gov by Monday, February 15.

7. What if I am busy during the time of the meeting or don't feel comfortable speaking during the meeting?

You can still provide input to the FDA! From now until May 10, you can submit a written comment about your experience living with vitiligo. Click here to view the full instructions and to submit your comment.

8. What topics will I be able to discuss at the meeting or in my written comment?

PFDD meetings focus on two topics: 1) what it is like to live with a specific disease or condition and how the disease or condition affects your daily life and 2) your experiences with treatments for that disease or condition. Specific topics that will likely be covered at the meeting include:

- The aspects of vitiligo that have the biggest impact on your life (such as depigmentation, itching, sensitivity to sunlight).
- How your vitiligo has changed over time.
- Activities that you would like to do but can't or won't do as fully because of your vitiligo.
- What worries you most about your vitiligo.
- What, if anything, you are currently doing to treat your vitiligo or what treatments you have tried in the past.
- How well those treatments work.
- The downsides of any treatments you currently do or have done in the past.
- What factors you take into account when considering a treatment for your vitiligo.
- Short of a cure, what would an ideal treatment for vitiligo look like?

9. Are there any topics I shouldn't mention at the meeting or in my written comments?

Remember that your objective should be to help the FDA understand what it is like to live with vitiligo and what you think about current and potential future treatments. The FDA has organized this meeting to learn from members of the vitiligo community, so you should not use this meeting to criticize the FDA, physicians, or pharmaceutical companies. Although health insurance and the cost of healthcare are important issues, those topics are outside of the FDA's role and should not be a focus for your remarks at the meeting or written comments.

10. I don't have vitiligo, but I have a partner, family member, or friend who has it. Can I participate in the meeting?

Yes! You are welcome to register for the meeting to show your support for people with vitiligo. If you are a parent of a child (under 18) with vitiligo, we encourage you to consider applying to be a panelist at the meeting or submitting a written comment about your child's experience with the condition.

11. I am a clinician or researcher who treats or studies vitiligo. Can I participate in the meeting or submit a written comment?

Yes! Although PFDD meetings are largely designed for the FDA to hear from patients, clinicians and researchers often attend these meetings to show their support and learn more about the experiences of people living with the condition. During the meeting, there will be a public comment period when participants who don't have vitiligo will have an opportunity to make brief remarks. You are also welcome to submit a written comment about your experiences treating people with vitiligo.