







What is a PFDD Meeting?

Purpose of the meeting

The U.S. Food and Drug Administration created the <u>Patient-Focused Drug Development</u> <u>program</u> in 2012 to formally collect information about the patient perspective with regard to drug development – specifically, what people living with a disease consider to be meaningful treatment benefits and how they want to be involved in the drug-development process.

Since the program's creation, FDA has conducted more than 25 PFDD meetings. The agency also expanded the program to allow patient-advocacy organizations to host meetings; these are known as Externally-Led PFDD meetings.

Our Externally-Led PFDD Meeting will focus on schizophrenia. It is our chance to tell drug developers and FDA reviewers what we need from new treatments: what benefits we expect, and what risks we may be willing to tolerate if we can achieve those benefits.

How does it work?

PFDD and EL-PFDD meetings feature speaker panels of people living with a disease, their families, caregivers and patient advocates. Panelists discuss topics such as disease symptoms that are most important to them, the impact of a disease on their daily lives (and quality of life) and their experiences with current treatments.

FDA staff generally attend, as do people living with the disease; families and caregivers; drug developers; academic researchers; and healthcare providers. The meetings are open to the public. Our meeting will be held in the Washington, D.C., metro area, with a hybrid format that allows both in-person and remote participation.

What happens afterward?

After the meeting, we will create a Voice of the Patient Report that summarizes key themes from the discussions, includes detailed comments from participants and reports findings from the premeeting survey of patients and families that we'll launch early this summer. The VOP report is submitted to FDA and posted publicly online one to two months after the meeting.

The FDA uses all of this information "to inform decisions and oversight" throughout the drug-development process and during its review of drug-marketing applications.