Externally-led Patient-Focused Drug Development Meetings

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CDER and You: Keys to Effective Engagement
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Patient-focused drug development (PFDD) is a systematic approach to help ensure that patients’ experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation.
**Externally-led PFDD: The Opportunity**

- Patient organizations identify and organize **patient-focused collaborations** to generate public input on specific disease areas.

- PFDD meetings provide an important opportunity to **hear directly from patients**, patient advocates, and caregivers about the symptoms that matter most to them, the impact the disease has on patients’ daily lives, and patients’ experiences with currently available treatments.

- While FDA will be open to participating in a well-designed and well-conducted meeting, an externally-led PFDD meeting and any resulting products (e.g., surveys or reports) will **not be considered FDA-sponsored or FDA-endorsed**.
Planning a PFDD meeting

**KEY PARTICIPANTS:**
Patients, patient representatives, patient advocates

**TARGET AUDIENCE (LISTENING MODE):**
Regulatory/other federal agencies, medical product developers, researchers, healthcare professionals

**DO NOT HAVE TO BE STANDALONE MEETINGS:**
Consider incorporating PFDD-style sessions in annual conferences, scientific workshops, etc.

**FDA-led meetings can serve as a model:**
- Target disease areas where there is an identified need for patient input on topics related to drug development
- Main discussion topics: (1) Symptoms and daily impacts that matter most to patients and (2) current approaches to treatment
- Facilitator-led large group discussion, interactive webcast, discussion aids (e.g., polling tools)
- Meeting deliverables: Web recording, transcript, summary report

#PFDD
Key Considerations

Submit a letter of intent to CDER’s Office of Strategic Programs. Our team is here to serve as a helpful resource to you.

While we truly understand the effort it takes to plan a PFDD meeting, it can be done without being resource intensive!

The key to an insightful, robust, and informative PFDD meeting is active community outreach to ensure a representative group of patient perspectives in the room.

We must be respectful of the time of patients and their caregivers.
Meetings Strengthen Understanding of Disease and Treatment Burden

Patient input from meetings can support FDA staff:
- In conducting benefit-risk assessments for products under review, by informing the therapeutic context
- Advising drug sponsors on their development programs

It might also support drug development more broadly:
- Identify areas of unmet need in the patient population
- Identify or develop tools that assess benefit of potential therapies
- Raise awareness and channel engagement within the patient community

Meeting summary reports capturing patient experience data may be shared on FDA’s website:
- FDA’s External Resources or Information Related to Patients’ Experience webpage provides links to certain publicly available external reports and resources.
External Resources or Information Related to Patients’ Experience

This webpage is intended to facilitate public discussion of patient-focused drug development and evaluation. This webpage provides links to certain publicly available external reports and resources relating to patient experience data. The patient community, patient advocates, researchers, drug developers, and federal agencies may find these materials useful.

Please note that although FDA reviews the materials at these links before posting them to ensure that the materials are within the scope of the webpage, FDA does not assess their scientific merit or compliance with regulatory requirements. Our decision to post links to these materials does not reflect an endorsement of their authors, sponsors, or content.

For more information regarding what types of resources may be included on this webpage, how to submit a publicly available website link to FDA, and other general questions, please review our Frequently Asked Questions. We request that links include a cover page or similar opening statement as part of their report or resource to provide information about the authors, funding, and related information. For specific questions related to a report or resource, FDA recommends reaching out to the point of contact listed on this cover page.

Externally-led PFDD Meeting Reports or Other Stakeholder Meeting Reports

External Resources or Information Related to Patients’ Experience
CDER’s Patient-Focused Drug Development Homepage

Email: patientfocused@fda.hhs.gov