U.S. FOOD & DRUG ADMINISTRATION

Incorporating the Patient Voice into Clinical Trial Design and Conduct

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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.

#PFDD

Better integrating the patient's perspective at critical points in drug development and decision making

Identify and **measure** outcomes and burdens that matter most to patients

- **Design** better clinical studies
- **Recruit** potential patients
- **Retain** study participants

Integrate patient-reported outcomes and patient preference information **into BR assessments**

Better Communicate information about drugs to patients and providers to **facilitate** informed decision-making

Patients can provide:

- Natural History Data
- Input on relevance of research to patients
- Help defining eligibility criteria
- Input on meaningful endpoints
- Education to the patient community
- Input on protocol input and feasibility

- Increased awareness about trials
- Participant feedback on trial experience
- Input on informed consent content and processes
- Members of Data and Safety Monitoring boards
- Collaboration on post-marketing studies and surveillance initiatives

Resources are available on PFDD webpages

CDER Patient-Focused Drug Development Homepage

- Guidances
- COA Grant Program
- FDA-led PFDD Meetings
- Externally-led PFDD Meetings
- External Resources

- Browse upcoming meetings
- View past meeting materials
  - Slides, meeting recordings, transcript, agenda, summary report

Questions?
Email **PatientFocused@fda.hhs.gov**.

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