

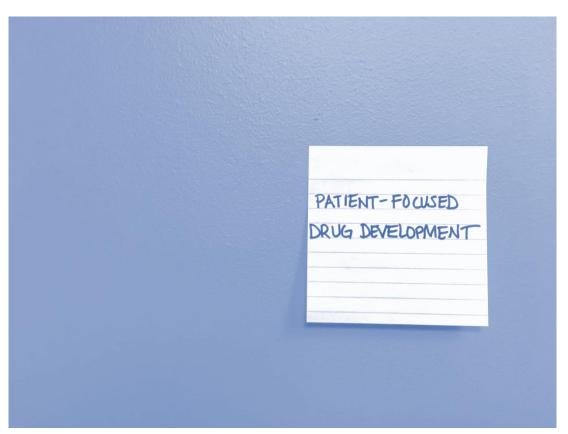
Incorporating the Patient Voice into **Clinical Trial Design and** Conduct

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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.





# 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

**Translational** 

- **Design** better clinical studies
- Recruit potential patients

**Clinical Studies** 

• 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

**Pre-market review** 

**Post-market** 

### 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 <u>PatientFocused@fda.hhs.gov</u>. To get updates about CDER's Patient-Focused Drug Development programs, subscribe to our <u>free email</u> <u>subscription service</u> by clicking on the button near the top of the <u>homepage</u>.