Patient Affairs Staff

Enhancing FDA Patient Engagement

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CDER and You Public Workshop
Keys to Effective Engagement
April 3, 2018

Patient Affairs Staff (PAS)

- Established December 2017
- Works closely with the medical product centers and other offices to support and complement patient engagement efforts
- Reports into the Principal Deputy Commissioner for Medical Products and Tobacco

Patient Engagement Collaborative

Patient Engagement Collaborative (PEC)

The FDA and the Clinical Trials Transformation Initiative (CTTI) are establishing an external group of patient organization and individual representatives to discuss topics about enhancing patient engagement in medical product development and regulatory discussions at FDA.

Patient Engagement Collaborative (PEC)

Why PEC?

- FDA listened
  - ✓Public comments from patients and other stakeholders recommended that FDA create an outside group to provide input on patient engagement across the FDA
- The laws
  - ✓Facilitated by recent legislation in both the 21st Century Cures Act and FDARA for fostering patient participation and incorporating patient experiences in the regulatory process
- A model
  - ✓The European Medicines Agency's Patients' and Consumers' Working Party (PCWP)

Patient Engagement Collaborative (PEC)

Membership Criteria

- Patients who have personal disease experience
- Caregivers who support patients, such as a parent, child, partner, other family member, or friend, and who have personal disease experience through this caregiver role
- Representatives from patient groups who, through their role in the patient group, have direct or indirect disease experience.

Patient Engagement Collaborative (PEC)

- Next Steps
  - 200 nominations received (closed January 29, 2018)
  - Review and select members
  - Schedule first meeting (TBD)

For more information:
FDA Voice Blog December 20, 2017
You Spoke, FDA Listened: New Patient Engagement Collaborative, Call for Nominations

Patient Experience Listening Sessions

Patient Experience Listening Sessions

- Memorandum of Understanding with the National Organization for Rare Disorders (NORD)
- Pilot listening sessions in rare diseases to enhance the incorporation of patient experience into regulatory discussions
- Assess value added to possibly expand

Patient Experience Listening Sessions

Next steps:

- Identify pilot therapeutic area
- Develop process with NORD
- Conduct pilot listening sessions
- Evaluate internal and external feedback
- Develop recommendations

Thank you

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