Evolution of Patient Engagement at the FDA

2022

- Center for Devices and Radiological Health launched the Total Product Life Cycle Advisory Program (TAP) pilot
- Final PFDD Guidance 2 released
- Draft PFDD Guidance 3 released
- Patients Matter: What is a Patient Listening Session? Video
- FDA Releases Action Plan for Rare Neurodegenerative Diseases, Including ALS
- FDA/NIH ACT for ALS Stakeholder Engagement Meeting

2023

- FDA/Duke Margolis Public Meeting on Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement
- Patients Matter: Patient Listening Session Testimonial Videos: Community Perspectives and FDA Staff Reflections
- PFDD meeting on Long-Covid
- Draft PFDD Guidance 4 released
- Five-year anniversary of Memorandum of Understanding with NORD on Patient Listening Sessions

2021

- Accelerating Access to Critical Therapies for ALS Act (ACT for ALS) signed into to law (Public Law 117-79)
- FDA Listening Session with transgender community (adults and adolescents)
- Article published in American Academy of Pediatrics (AAP) News about our first Patient Listening Session with only adolescent participants.
- About FDA: Patient Q&A document published.
- Patient Engagement Collaborative and EMA's PCWP inaugural annual meeting
- Federal Register Notice request for applications for new members of PEC
- Center for Biologics Evaluation and Research annual Patient Engagement and Regenerative Medicine (RegenMedEd) workshop series launched

2020

- COVID-19 patient resources webpage launched (retired)
- Final PFDD guidance 1 released
- FDA/Muscular Dystrophy Association webinar-COVID-19 impact on the community
- FDA/NORD listening session-COVID-19 impact on rare disease communities

2019

- Patients Ask FDA Webform launched
- Public workshop on PFDD workshop guidance 4
- Draft PFDD guidance 2 released
- Patients Matter Video Series launched

2018

- Memorandum of Understanding with National Organization For Rare Disorders launched the Patient Listening Session pilot program
- Patient Engagement Collaborative launched with Clinical Trials Transformation Initiative
- Center for Devices and Radiological Health Patient & Caregiver Connection program launched
- Public workshops on PFDD guidances 2 and 3 and draft PFDD guidance 1 released

2017

- Patient Affairs Staff (PAS) established in the Office of the Commissioner
- Public Workshop on PFDD guidance
- First PEAC meetings regarding medical devices

2016

- FDA and European Medicines Agency Patient Engagement Cluster created
- First Patient Council (internal) meeting held

2015

- Patient Preference Information framework and guidance for medical device decision making
- Patient Engagement Advisory Committee (PEAC) announced in the Federal Register

2013

- FDASIA Section1137 Internal working group examined ways to increase patient involvement in FDA processes
- Consumer-friendly form introduced in FDA's MedWatch system to report medical product problems

2012

- FDA launched For Patients on the web
- Patient-Focused Drug Development (PFDD) initiative launched

2008

- Patients and consumers encouraged to report medical product problems using FDA's existing MedWatch system

2001

- First FDA Patient Representative Program® role expanded to serve as consultants to scientific and regulatory reviewers

1996

- First FDA Patient Representatives® received voting rights on advisory committees

1993

- Office of AIDS Coordination renamed to Office of AIDS and Special Health Issues to include cancer patients and other serious/life-threatening diseases
- First FDA Patient Representative® served on an advisory committee

1988

- Office of AIDS Coordination established