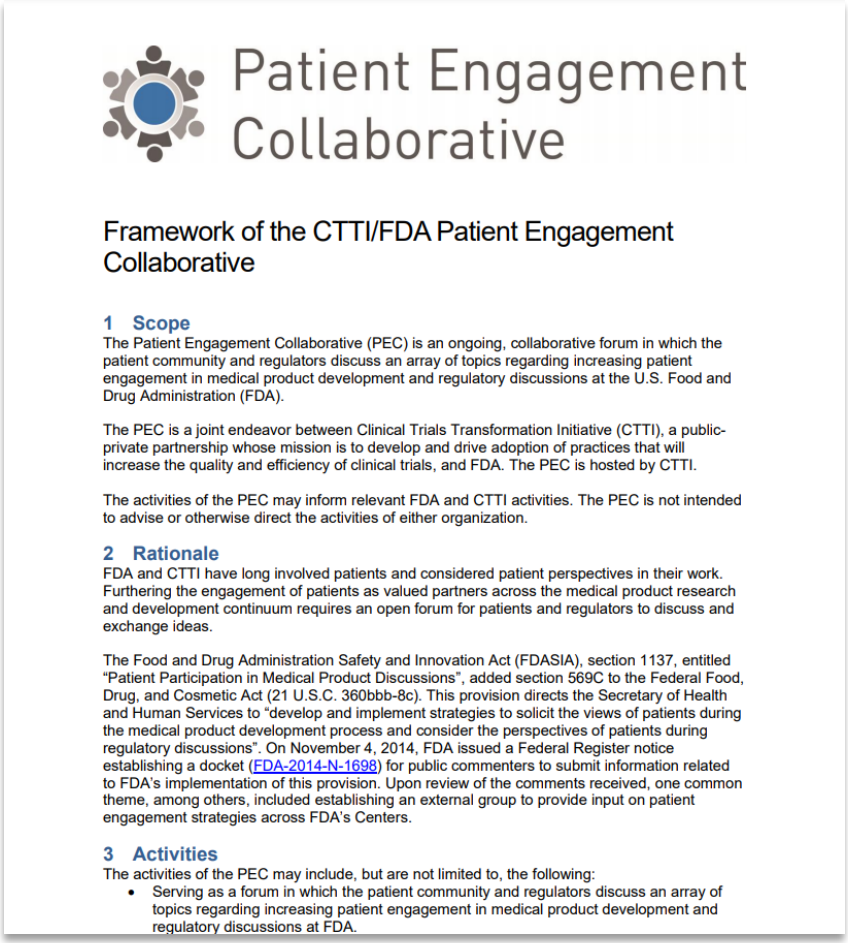
What is the Patient Engagement Collaborative (PEC)?

- Established 2018
- FDA & Clinical Trials Transformation Initiative (CTTI)
- Modeled on the EMA's Patients and Consumers Working Party (PCWP)
- Purpose: Discussions about engaging patients in medical product development and regulatory discussions

Current PEC Members

- Carol Abraham
- Ronald Bartek
- Julie Breneiser
- Sneha Dave
- Maria De Leon
- Anne Hall
- Elizabeth Joniak-Grant
- Sharon Lagas
- John Linnell
- Isabelle Lousada
- James Pantelas
- Lawrence "Rick" Phillips
- Philip Posner
- Lynne Quittell
- Traceann Rose
- Adrienne Shapiro

Patient Engagement Collaborative (PEC)



Patient Engagement Collaborative

Framework of the CTTI/FDA Patient Engagement Collaborative

1 Scope

The Patient Engagement Collaborative (PEC) is an ongoing, collaborative forum in which the patient community and regulators discuss an array of topics regarding increasing patient engagement in medical product development and regulatory discussions at the U.S. Food and Drug Administration (FDA).

The PEC is a joint endeavor between Clinical Trials Transformation Initiative (CTTI), a public-private partnership whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials, and FDA. The PEC is hosted by CTTI.

The activities of the PEC may inform relevant FDA and CTTI activities. The PEC is not intended to advise or otherwise direct the activities of either organization.

2 Rationale

FDA and CTTI have long involved patients and considered patient perspectives in their work. Furthering the engagement of patients as valued partners across the medical product research and development continuum requires an open forum for patients and regulators to discuss and exchange ideas.

The Food and Drug Administration Safety and Innovation Act (FDASIA), section 1137, entitled "Patient Participation in Medical Product Discussions", added section 569C to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c). This provision directs the Secretary of Health and Human Services to "develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions". On November 4, 2014, FDA issued a Federal Register notice establishing a docket (FDA-2014-N-1698) for public commenters to submit information related to FDA's implementation of this provision. Upon review of the comments received, one common theme, among others, included establishing an external group to provide input on patient engagement strategies across FDA's Centers.

3 Activities

The activities of the PEC may include, but are not limited to, the following:

- Serving as a forum in which the patient community and regulators discuss an array of topics regarding increasing patient engagement in medical product development and regulatory discussions at FDA.

- Public-private partnership with CTTI
- Information exchange between patient community representatives and FDA
- Topics about enhancing patient engagement in regulatory discussions (not specific medical products) through communications/education
- No confidential commercial information is discussed
- Activities may inform relevant FDA and CTTI work or initiatives
- Not intended to advise or otherwise direct the activities of either organization
- Meeting summaries are made public

Representatives and Membership Selection

Representatives from the patient community include:

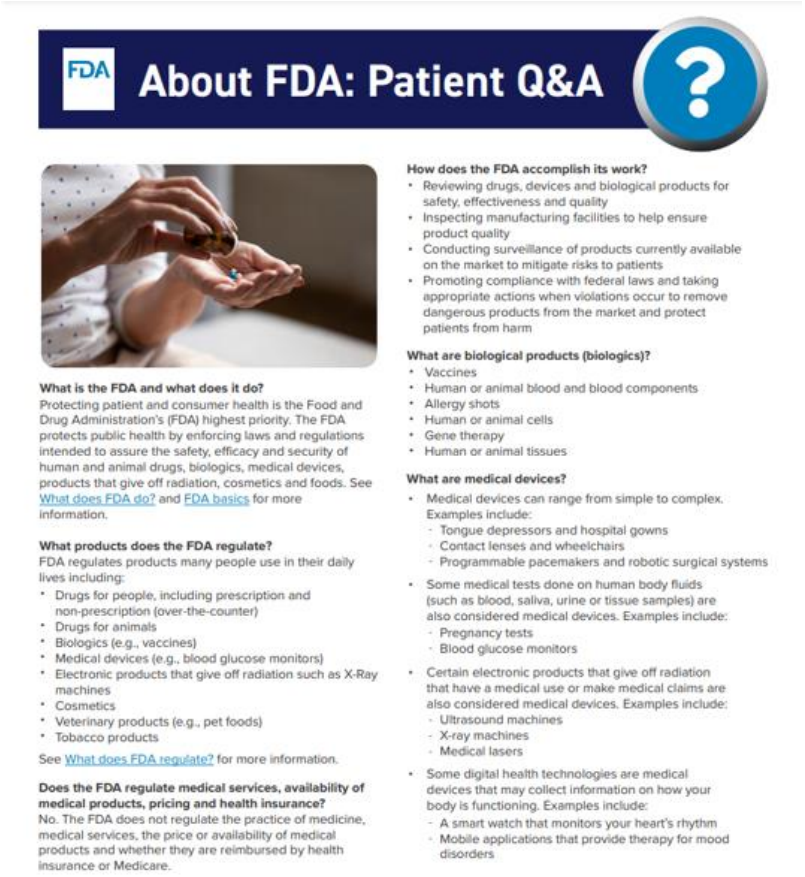
- Patients who have personal disease experience.
- Caregivers who have personal experience supporting someone with a health condition (e.g., a parent, child, partner, family member or friend).
- Representatives from patient groups who have direct or indirect disease experience.

Members selected through an open application process:

- Some members affiliated with patient groups/organizations
- Some are individual members (not required to be affiliated with a patient organization)
- Caregivers (past or present) are included
- Diversity of members is important

Current Diseases/Conditions Represented: Sickle Cell, Parkinson's, Limb Girdle Muscular Dystrophy, Fibromyalgia, AL Amyloidosis, Lung Cancer, Cerebral Palsy, Vasculitis, COPD, Gorlin Syndrome, Arthritis, Cystic Fibrosis, Multiple Sclerosis, Friedreich's Ataxia, Alport Syndrome, Ulcerative Colitis

Educational Resources for Patients



FDA About FDA: Patient Q&A

What is the FDA and what does it do?
Protecting patient and consumer health is the Food and Drug Administration's (FDA) highest priority. The FDA protects public health by enforcing laws and regulations intended to assure the safety, efficacy and security of human and animal drugs, biologics, medical devices, products that give off radiation, cosmetics and foods. See What does FDA do? and FDA basics for more information.

What products does the FDA regulate?
FDA regulates products many people use in their daily lives including:

- Drugs for people, including prescription and non-prescription (over-the-counter)
- Drugs for animals
- Biologics (e.g., vaccines)
- Medical devices (e.g., blood glucose monitors)
- Electronic products that give off radiation such as X-Ray machines
- Cosmetics
- Veterinary products (e.g., pet foods)
- Tobacco products

See What does FDA regulate? for more information.

Does the FDA regulate medical services, availability of medical products, pricing and health insurance?
No. The FDA does not regulate the practice of medicine, medical services, the price or availability of medical products and whether they are reimbursed by health insurance or Medicare.

How does the FDA accomplish its work?

- Reviewing drugs, devices and biological products for safety, effectiveness and quality
- Inspecting manufacturing facilities to help ensure product quality
- Conducting surveillance of products currently available on the market to mitigate risks to patients
- Promoting compliance with federal laws and taking appropriate actions when violations occur to remove dangerous products from the market and protect patients from harm

What are biological products (biologics)?

- Vaccines
- Human or animal blood and blood components
- Allergy shots
- Human or animal cells
- Gene therapy
- Human or animal tissues

What are medical devices?

- Medical devices can range from simple to complex. Examples include:
  - Tongue depressors and hospital gowns
  - Contact lenses and wheelchairs
  - Programmable pacemakers and robotic surgical systems
- Some medical tests done on human body fluids (such as blood, saliva, urine or tissue samples) are also considered medical devices. Examples include:
  - Pregnancy tests
  - Blood glucose monitors
- Certain electronic products that give off radiation that have a medical use or make medical claims are also considered medical devices. Examples include:
  - Ultrasound machines
  - X-ray machines
  - Medical lasers
- Some digital health technologies are medical devices that may collect information on how your body is functioning. Examples include:
  - A smart watch that monitors your heart's rhythm
  - Mobile applications that provide therapy for mood disorders

- About FDA: Patient Questions and Answers
  - September 2021
  - Printable PDF for community outreach
- Created webpages where patients can learn about FDA patient engagement opportunities and activities

Patient Matters Video Series

Patients Matter: How Rare Disease Patients Can Move Scientific Discovery Forward

Learn about how patients, caregivers, and advocates can get involved in natural history studies and clinical trials to help scientists develop treatments for patients with rare diseases.

- Series of short videos to educate patients and stakeholders about the importance of patient engagement and regulatory issues.
- PEC helped locate patients to provide personal stories and some members also featured in videos.

https://www.fda.gov/patients/learn-about-fda-patient-engagement/patients-matter-video-series