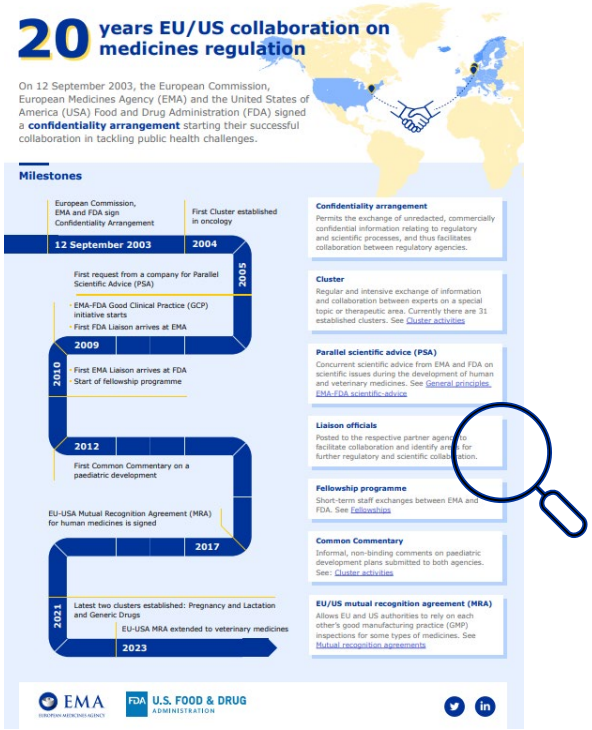
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Collaboration with US FDA

Patient engagement

Maria Mavris, Patient liaison

EMA-FDA collaborations



Liaison officials

Posted to the respective partner agency to facilitate collaboration and identify areas for further regulatory and scientific collaboration.

FDA liaison to EMA – Katherine Tyner

EMA liaison to FDA – Anabela Marcal

EMA-FDA Patient engagement cluster

Established: 2016 following fellowship exchange between EMA and FDA (2014 and 2015) and with support from liaisons

Meeting frequency: quarterly by teleconference

Participants: EMA, FDA – now includes Health Canada

The objective of the cluster is to share best practices on involving patients along the medicine's regulatory lifecycle, to further improve and extend both agencies' current actives in this area.

Terms of reference for the European Medicines Agency / Food and Drug Administration cluster on patient engagement

PCWP and Patient Engagement Collaborative (PEC)

Patient Engagement Collaborative (PEC)

- Hosted by Clinical Trials Transformation Initiative(CTTI) and supported by FDA's Patient Affairs
- Modeled on EMA's Patients' and Consumers' Working Party (PCWP)
- Inaugural group began in 2018
- Comprised of 16 wide-ranging representatives of the patient community (patients, caregivers, patient advocates)
- Serve 2-year terms

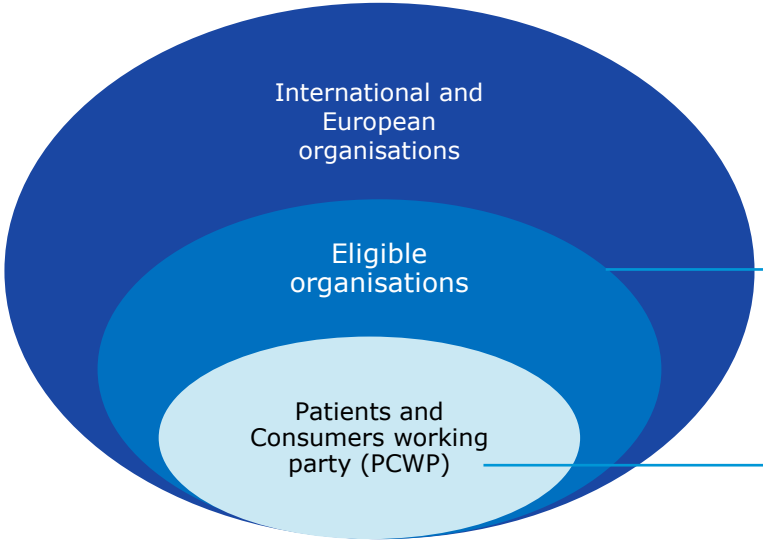
https://www.fda.gov/patients/learn-about-fda-patient-engagement/patient-engagement-collaborative

Representatives

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

Patients and Consumers Working Party (PCWP)



PCWP consists of 30 members:

- 22 representatives appointed from EMA's eligible patients and consumers organisations;
- 6 representatives appointed by EMA's scientific committees;
- 1 Chairperson elected from patient members (PCWP Co-Chair);
- 1 Chairperson nominated by EMA (EMA Co-Chair)
- Mandate, Rules of Procedure and 3 year Work Plan developed together

Observers from:

- EMA Management Board;
- European Commission;
- Healthcare Professionals Working Party (HCPWP);

All members' declarations of interests published in European experts list.

Joint PCWP-PEC meetings

2021	focused on experiences on patient information and communication and youth engagement
2022	lessons learnt from COVID and emerging issues in patient engagement
2023	addressed the topic of decentralised clinical trials (DCT) and included speakers and patients from the US and the EU describing different perspectives and experiences of DCT.
2024	brought the topic of patient-reported outcomes with spotlights on two workshops followed by a panel discussion with representatives from PEC and PCWP

Thank you