

AGENDA

Joint Meeting of CTTI/FDA Patient Engagement Collaborative (PEC) and EMA Patients' and Consumers' Working Party (PCWP)

June 18, 2024

9:00 am – 11:30 am (EDT) / 15.00 – 17.30 (CEST)

8:45/14.45 *Meeting open early for optional icebreaker and audio check*

9:00 / 15.00 **Welcome & Overview of Agenda**

Facilitator: Morgan Hanger, Executive Director, CTTI

- ▶ Welcome and Setting the Scene

9:10 / 15.10 **Presentations**

Facilitator: Maria Mavris, European Medicines Agency

- ▶ Speaker 1: Caroline Voltz, EMA
Team Lead, Oncology, Advanced Therapies and Haematological Diseases Office

Presentation: EORTC Workshop: How can patient-reported outcomes (PRO) and health-related quality of life (HRQoL) data could inform regulatory decisions.

- ▶ Speaker 2: Fraser Bocell, CDRH, FDA
Psychometrician, Division of Patient-Centered Development

Presentation: FDA-CDRH-NIH Workshop on Patient-Reported Outcomes and Vision Related Quality of Life Questionnaires

- ▶ Question & Answer

9:40 / 15.40 **Break**

9:55 / 15.55 **PEC and PCWP Member Reactions**

Facilitator: Wendy Slavit, U.S. Food and Drug Administration

- ▶ PCWP Member: Silene ten Seldam
Myeloma Platform Europe
- ▶ PEC Member: Ceciel Rooker
International Foundation for Gastrointestinal Disorders (IFFGD)

► Discussion

Panelist 1: PEC Member: Ceciel Rooker

Panelist 2: PCWP Member: Silene ten Seldam

Panelist 3: EMA: Caroline Voltz

Panelist 4: FDA: Fraser Bocell

11:10 / 17.10 Suggestions for Next Year

Facilitator: Andrea Furia-Helms, U.S. Food and Drug Administration

11:20/ 17.20 Final Comments and Adjourn

Facilitator: Andrea Furia-Helms, U.S. Food and Drug Administration

Background Information

About the EMA:

<https://www.ema.europa.eu/en>

About the PCWP:

<https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/patients-consumers-working-party>

About the FDA:

<https://www.fda.gov/>

About the PEC:

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

Resources: Patient Experience Data and Patient Reported Outcomes

FDA

Virtual Public Workshop – Patient-Reported Outcomes and Vision Related Quality of Life Questionnaires, September 29, 2023

<https://www.fda.gov/medical-devices/medical-devices-news-and-events/virtual-public-workshop-patient-reported-outcomes-and-vision-related-quality-life-questionnaires>

<https://www.nei.nih.gov/about/news-and-events/events/workshop-patient-reported-outcomes-and-vision-related-quality-life-questionnaires>

<https://www.fda.gov/about-fda/center-devices-and-radiological-health/division-patient-centered-development>.

EMA

EMA and European Organisation for Research and Treatment of Cancer (EORTC) workshop: How can patient-reported outcomes (PRO) and health-related quality of life (HRQoL) data inform regulatory decisions?

<https://www.ema.europa.eu/en/events/ema-european-organisation-research-treatment-cancer-eortc-workshop-how-can-patient-reported-outcomes-pro-health-related-quality-life-hrqol-data-inform-regulatory-decisions>