

EFA Meet & Greet the EU training

The new European Medicines Agency (EMA) and Clinical Trials Regulation: what role for patients?

Date & Time

27 October 2022
9:00 - 16:00 CET, in-person training

Location

Prestige Room
367, Avenue Louise
B-1050 Brussels

Context

The Meet & Greet the EU series is part of EFA's 2022 Capacity Building Programme. Following our 2021 Meet & Greet with the EMA on patients' engagement, this session aims to further develop Member knowledge of the form and function of the European Medicines Agency (EMA), the new EU regulation expanding its mandate, and the entry into force of the Clinical Trials Regulation and what it all means for patients living with respiratory and allergic diseases.

EFA Objective

INFORM: EFA builds patient evidence, momentum, and capacity for change in prevention, care and participation for people with allergy and airways diseases.

Specific Objectives

- Increase Member understanding of the EMA's extended mandate for a greater role in crisis preparedness and management for medicinal products and medical devices, and what it means for patients.
- Improve Member knowledge of the Clinical Trials Regulation (Regulation (EU) No 536/2014), its tools and functions as well as the implications for patients participating in clinical trials, including recruitment, consent and access to information

Target audience

Staff, volunteers and members of the Board of EFA members. Open also to patients non-attached to an EFA member, provided they belong to patient groups active in the field of respiratory disease.

Expected attendance

10 allergy and respiratory patients, patient advocates and/or carers in person, with the potential for more virtually. EFA staff and speakers will also be in attendance.

Welcome & Introduction

01

9:00 - 9:30
(30 minutes)

Session type:
Oral Presentation /
Keynote Address

Session Description

This Session will kick off the meeting with a brief round of introduction and set the stage for the day with the following:

- Objectives of the meeting.
- Keynote speech - Importance of patient involvement in all stages of medicines R&D.

Session Objectives

- Welcome all participants.
- All participants make introductions.
- Set an inspirational tone to peak the audience interest in the coming sessions.

Moderator(s):

- EFA Representative

Speaker(s):

- Olivia Fulton, Severe asthma patient advocate, Asthma +Lung UK

EMA's role

02

9:30 - 10:15
(45 minutes)

Session type:
Oral Presentation

Session Description

Following the 2021 Meet & Greet with EMA, this session will review EMA's key competencies and relevance to patients including:

- EMA centralised authorisation procedure.
- Interaction with national competent authorities.
- EMA's activities for patient engagement.

Session Objectives

- Establish a basic understanding of EMA's form and function as a European institution.
- Help participants see the connection between the EMA's work and their respective national authorities – understanding the basics of medicines R&D taxonomy.
- Highlight opportunities for patient engagement in EMA generally.

Moderator(s):

- EFA Representative

Speaker(s):

- Maria Mavris, Patient Relations, Public and Stakeholder Engagement Department, EMA

Coffee Break

**10:15 - 10:45
(30 minutes)**

EMA's extended mandate

03

10:45 - 12:00
(75 minutes)

Session type:
Oral Presentation
with Q&A

Session Description

This session aims to help patients understand the importance and relevance of the EMA's extended mandate for patients including their role in:

- Shortages on medicines and critical in-vitro diagnostics and medical devices.
- Coordination during health crisis.
- EU's coordinated medical response to future health crises.

It will also feature some time for Q&A with the speakers.

Session Objectives

- Give an overview of the EMA's extended mandate and its main areas of impact.
- Highlight EU coordination relevant to national coordinated responses to future health crises.

Moderator(s):

- EFA Representative

Speaker(s):

- Inga Abed, Medical Writer, EMA
- Anne Simon, DG HERA (Health and Emergency Response Authority), HERA4 Emergency Office, Head of Unit

Lunch Break

**12:00 - 13:30
(90 minutes)**

The EU Regulation on clinical trials

04

13:30 - 14:30
(60 minutes)

Session type:
Oral Presentation
with Q&A

Session Description

This session will detail the new EU Clinical Trials Regulation (Regulation (EU) No536/2014), its tools and functions including:

- What changed from January 2022?
- Clinical Trials Information System.
- Roadmap Initiative to Good Lay Summary Practice.
- Q&A with participants.

Session Objectives

- Increase participant knowledge of the impact of the new EU Clinical Trials Regulation on patients.
- Highlight new tools and opportunities for increased patient engagement and patient education related to clinical trial participation.

Moderator(s):

- EFA Representative

Speaker(s):

- Dr. PhD Marta Valenciano, Lead epidemiologist, Policy-Strategy Unit, DG SANTE, European Commission
- Dr Solange Corriol-Rohou, European Forum for Good Clinical Practice (EFGCP) Board Member and Senior Director Regulatory Affairs & Policy, Europe at AstraZeneca

Coffee Break

**14:30 - 14:45
(30 minutes)**

Multistakeholder Perspectives of the EU Clinical Trials Regulation

05

14:45 - 15:45
(60 minutes)

Session type:
Panel Discussion

Session Description

- This session aims to Encourage analytical thinking about the impact of the EU Clinical Trials Regulation on participants' respective patient communities.
- Increase understanding of different stakeholder perspectives and considerations.
- Highlight future challenges and opportunities for patient engagement in the medicines R&D process.

Session Objectives

- Encourage analytical thinking about the impact of the EU Clinical Trials Regulation on participants' respective patient communities.
- Increase understanding of different stakeholder perspectives and considerations.
- Highlight future challenges and opportunities for patient engagement in the medicines R&D process.

Moderator(s):

- EFA Representative

Speaker(s):

- Patient Perspective
 - Olivia Fulton, Severe asthma patient advocate, Asthma +Lung UK
- Civil Society Perspective
 - Dr Solange Corriol-Rohou, European Forum for Good Clinical Practice (EFGCP) Board Member and Senior Director Regulatory Affairs & Policy, Europe at AstraZeneca
- Industry Perspective
 - Sini Eskola, Director, Team Leader, Regulatory Strategy, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Closing Remarks

06

15:45 - 16:00
(15 minutes)

Speaker(s):

- EFA Representative