



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instrument for Pre-accession Assistance (IPA) advanced EMA training on Clinical Trials, Pharmacovigilance and Shortages

16-17 November 2023 - Amsterdam

Chairs: Ivo Claassen, Michiel Hendrix and Judit Barniol (EMA)

Programme



Registration and welcome coffee / 08:30-09:00

Official welcome and opening remarks

Ivo Claassen - EMA Deputy Executive Director / 09:15-09:30

Morning session

Chair: Ivo Claassen – Deputy Executive Director, EMA

Seminar 1 - Management of shortages

Moderators: Maria Jesus Alcaraz Tomas (EMA) and Siofradh McMahon (EMA)

09:30-10:45

Coffee break / 10:45-11:15

Seminar 2 - Communication and stakeholder engagement in medicines regulation

Moderator: Morgane de Verdiere (EMA)

11:15-12:30

Lunch (EMA canteen) / 12:45-13:30

Afternoon session

Chair: Michiel Hendrix, International Affairs Officer, EMA

Seminar 3 - Evaluation of PBRER (PSUSA procedure)

Moderators: Lina Albakri (EMA), Benjamin Pelle (EMA) and Menno van der Elst (MEB)

13:30-14:45

Coffee break / 14:45-15:15

Seminar 4 - Use of real-world data (RWD) in pharmacovigilance and pharmacoepidemiology

Moderator: Catherine Cohet (EMA)

15:15-16:45

*Group photo
Networking event, EMA Sky lounge (18th floor)
17:00-20:00*

Registration and welcome coffee / 08:30-09:00

Introduction Day 2

Chair: Michiel Hendrix, International Affairs Officer, EMA / 09:15-09:30

Morning session

Chair: Judit Barniol, International Affairs Officer, EMA

Seminar 5 - Safety of medicines in special populations (children, pregnant and lactating women and elderly)

Moderators: Viola Macolic Sarinic (EMA) and Charlotte Bakker (EMA)

09:30-10:45

Coffee break / 10:45-11:15

Seminar 6 - Evaluation of effectiveness of risk minimization measures

Moderators: Maria Escudeiro dos Santos (EMA) and Thomas Goedecke (EMA)

11:15-12:30

Lunch (EMA canteen) / 12:45-13:30

Afternoon session

Chair: Michiel Hendrix, International Affairs Officer, EMA

Seminar 7 - Setting the scene: the clinical trials regulation

Moderators: Laura Pioppo (EMA) and Iordanis Gravanis (EMA)

13:30-14:45

Coffee break / 14:45-15:15

Seminar 8 - GCP inspections – overview and introduction

Moderator: Tiina Johanna Holmberg (EMA)

15:15-16:30

Closing remarks

Michiel Hendrix, International Affairs Officer, EMA

16:30-16:45

About this event

This event is part of the European Commission funded Instrument for Pre-Accession Assistance (IPA) programme.

The main objective of this training is to prepare the integration of current candidate countries and potential candidates into the European Union regulatory systems by bringing them in closer alignment with the Acquis Communautaire in the field of medicines regulation.

About the European medicines regulatory system and EMA

The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 30 EEA countries (27 EU Member States plus Iceland, Liechtenstein and Norway), the European Commission and EMA. This network makes the EU regulatory system unique.

The network is supported by a pool of some four thousand experts drawn from across Europe, allowing it to source the best possible scientific expertise for the regulation of medicines in the EU and to provide scientific advice of the highest quality.

EMA and the Member States cooperate and share expertise in the assessment of new medicines and of new safety information. They also rely on each other for exchange of information in the regulation of medicines, for example regarding the reporting of side effects of medicines, the oversight of clinical trials and the conduct of inspections of medicines' manufacturers.

Venue

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How to find us



Welcome to EMA!