HMA/EMA Multi–stakeholder workshop on Artificial Intelligence (AI) - enabling the safe and responsible use of AI

5 November 2024
Hybrid meeting / EMA, Amsterdam

The HMA/EMA's vision for Artificial Intelligence (AI) is for a regulatory system harnessing the capabilities of AI for personal productivity, process automation and systems efficiency, increased insights into data and strengthened decision-support for the benefit of public and animal health.

The HMA/EMA 2024 multi-stakeholder workshop on Artificial Intelligence follows on from AI workshops in 2021 and 2023 and is the first multi-stakeholder AI workshop under the new HMA/EMA multi-annual AI workplan.

The workshop objectives are to:

- Update on state-of-the-art of AI developments with keynote speakers.
- Update stakeholders on:
  - policy and legislative environment;
  - HMA/EMA activities on AI.
- Discuss with stakeholders and experts:
  - progress of the multi-annual AI workplan and possible updates;
  - AI use cases in the medicine lifecycle.

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08:30 Joining and technical checks

09:00 Opening and keynotes

Welcome

Peter Arlett (EMA) & Jeppe Larsen (DKMA)
Big Data Steering Group Co-chairs *5′*

Opening remarks

Emer Cooke (Executive Director, EMA) ***5′***
Karl Broich (President, BfArM) ***5′***
Marco Marsella (Director, EC DG SANTE.C) ***5′***

Keynotes

Jan Beger (GE Healthcare) ***20′***
Milana Trucl (EPF) ***20′***
Petra Ritter (Berlin Institute of Health) ***20′***
Andrew Bate (GSK) ***20′***

Questions and answers ***20′***

11:00 Break

11:15 Session 1: From AI policy to medicines regulation

Moderators: Marco Marsella (EC), Zaide Frias (EMA)

Session introductions *5′*

Presentation – Legal framing: EU AI Act and AI legal ecosystem ***15′***
Laura Jugel (AI Office, EC)

Questions and answers ***5′***

Presentation – Regulatory framing: AI Reflection Paper ***15′***
Gabriel Westman (MPA)

Questions and answers ***5′***

12:00 Lunch

13:00 Session 2: AI applications - Use cases in medicines lifecycles

Moderators: Manuela Messelhäußer (PEI), Hilmar Hamann (EMA)

Session introductions *5'*

Knowledge graphs for precision medicine ***10'***
Maria Sorokina (EFPIA)

Applying AI in ICSR management ***10'***
Hans-Jörg Römming (EFPIA)

Assessing the use of AI in neo-antigen prediction pipelines ***10'***
Liam Childs (PEI)

AI@MPA - an AI toolbox for medicines regulation ***10'***
Gabriel Westman (MPA)

How EMA is advancing AI Integration and Innovation ***10'***
Joaquim Berenguer Jornet (EMA)

Questions and answers ***15'***

14:10 Session 3: AI applications: Research priorities

Moderators: Marjon Pasmooij (MEB), Emmanuel Cormier (EMA)

Session introductions *10'*

Presentation – Patients view ***10'***
Julian Isla (DSEF)

Presentation – Academia view ***10'***
Flora Musuamba Tshinanu (University of Namur)

Presentation – HCP view ***10'***
Margarita Kirienko (Fondazione IRCCS Istituto Nazionale dei Tumori)

Presentation – MedTech view ***10'***
Annika Eberstein (COCIR)

Presentation – Researcher view ***10'***
Niklas Norén (UMC)

Panel discussion with speakers ***30'***

Session wrap-up *5'*

15:45 Break

16:00 Session 4: HMA/EMA AI workplan: Taking stock and planning forward

Moderators: Peter Arlett (EMA) & Jeppe Larsen (DKMA)
Session introductions *5'*

Overview of the HMA/EMA multi-annual AI workplan ***10'***
Luis Pinheiro (EMA)

Panel discussion ***45'***

Panelists:

Tala Fakhouri (FDA)
Thomas Brookland (EFPIA)
Florence van Hunsel (Netherlands Pharmacovigilance Centre Lareb)
Jesús Rueda Rodríguez (MedTech)
Tjalling van der Schors (EAHP)
Jelena Malinina (EURORDIS)

Questions & Answers ***30'***

17:30 Closing remarks

Wrap– up and next steps ***10'***
Peter Arlett (EMA) & Jeppe Larsen (DKMA)
Big Data Steering Group Co-chairs

Data protection note

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At certain points throughout the meeting, participants will be able to ask questions or give their input via the audience interaction tool Slido. Please go to Slido and enter the event code (#AIworkshop) and passcode (05112024). Interaction via Slido is voluntary, and you may opt to remain anonymous.

Abbreviations

BfArM - Federal Institute for Drugs and Medical Devices
COCIR - European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DKMA - Danish Medicines Agency
DSEF - Dravet Syndrome European Federation
EAHP - European Association of Hospital Pharmacists
EC – European Commission
EFPIA - European Federation of Pharmaceutical Industries and Associations
EMA – European Medicines Agency
EMRN - European Medicines Regulatory Network
EPF - European Patients' Forum
EURORDIS - European Organisation for Rare Diseases
FDA - Food and Drug Administration
MPA - Swedish Medical Products Agency
MEB – Medicines Evaluation Board
PEI - Paul-Ehrlich-Institut
UMC - Uppsala Monitoring Centre