Multi-stakeholder workshop on Pharmacogenomics

24 September 2024
Hybrid meeting / EMA, Amsterdam

Pharmacogenomics investigate the role of the genome in individualized drug response. Given the increasing amount of genomic data and large genomic databases emerging from health records, it is fundamental to leverage such data to explore novel opportunities for improved healthcare solutions for European citizens.

In line with strategic goals set out in the EMA Regulatory Science to 2025, the European medicines agencies network strategy to 2025, and the current workplan of the joint Heads of Medicines Agency (HMA)/EMA Big Data Steering group (BDSG), the main purpose of this conference is to highlight the relevance of pharmacogenomics for health and medicine regulation, to **discuss how pharmacogenomics can guide patients' treatment and can contribute to the safety of medicines, and to discuss how to promote the implementation of pharmacogenomics in clinical practice.**

In particular, the objectives of this event are to:

- Identify priority areas for additional regulatory action to promote the clinical implementation of pharmacogenomics.

- Discuss how medicines regulators can facilitate the uptake of genomics by national healthcare systems.
- Discuss how to leverage genomic data linked to real-world data sources with examples of current studies using such data.
- Discuss how to increase the regulatory impact of EU-funded projects in personalised medicine.

The outcome of the workshop will inform a roadmap towards the clinical implementation of pharmacogenomics in Europe.

Multi-stakeholder workshop on Pharmacogenomics

08:45 Joining and technical checks

09:00 Welcome and opening

Opening remarks from EMA **10'**
Emer Cooke, EMA

Opening remarks from European Commission **10'**
Irene Norstedt, DG Research and Innovation, EC

Introduction to the programme **5'**
Emmanuel Cormier, EMA

09:25 Session 1: Pharmacogenomics – current regulatory state of play and areas that would benefit from additional action

Co-chairs:
Niklas Blomberg, IHI Innovative Health Initiative, Belgium
Jessica Mwinyi, Medical Products Agency (MPA), Sweden
Session introductions *5'*

Why Pharmacogenomics is important for public health **15'**
María J Lamas, Agency for Medicines and Health Products (AEMPS), Spain

Current state of the art in Pharmacogenomics - a regulatory perspective **15'**
Marc Maliepaard, Medicines Evaluation Board (MEB), The Netherlands

Overview of medicinal products with PGx information in the SmPC **15'**
María Gordillo-Marañon, Agency for Medicines and Health Products (AEMPS), Spain

Questions and answers **20'**

10:30 Coffee break

11:00 Session 2: Implementation of pharmacogenomics by healthcare systems

Co-chairs:
Falk Ehmann, EMA
Carmen Laplaza Santos, DG Research and Innovation, EC
Session introductions *5'*

Pharmacogenomics implementation in Spain **15'**
Adrián Llerena Ruiz, Extremadura University

Pharmacogenomics implementation in the UK **15'**
Munir Pirmohamed, University of Liverpool

Pharmacogenomics implementation in Belgium **15'**
Jolyce Bourgeois, Belgian Health Care Knowledge Centre (KCE)

Pharmacogenomics implementation in Germany **15'**
Catharina Scholl, Federal Institute for Drugs and Medical Devices (BfArM)

Questions and answers **20'**

12:30 Lunch

13:30 Session 3: How to leverage genomic data for evidence generation

Co-chairs:
Patrice Verpillat, EMA
Aimad Torqui, Medicines Evaluation Board (MEB), The Netherlands
Session introductions *5'*

Navigating the complexities: pitfalls and opportunities in designing clinical pharmacogenomic studies **15'**
Magnus Ingelman-Sundberg, Karolinska Institute, Sweden

Considerations on data sources and data types **15'**
Sulev Reisberg, Tartu University, Estonia

Pharmacogenomics in real-world data studies **15'**
Daniel Prieto-Alhambra, Oxford University, UK
Junqing Xie, Oxford University, UK

HMA-EMA Catalogues on Real-World Data sources and studies **15'**
Stefania Simou, EMA

Questions and answers **20'**

15:00 Coffee break

15:30 Session 4: The future of pharmacogenomics – next steps, challenges for implementation

Co-Chairs:
Peter Arlett, EMA
Irene Norstedt, EC
Session introductions *5'*

Panel discussion **60'**

Panellists:

Patient organisation perspective
Francois Houÿez, Eurordis

Healthcare professional perspective
Vera Deneer, Utrecht University Medical Center, The Netherlands

Academia perspective
George Patrinos, University of Patras, Greece
Jesse Swen, Leiden University Medical Center, The Netherlands

European Partnership for Personalised Medicine perspective
Juan Riese Jorda, EP PerMed

Industry perspective
Marius Garmhausen, EFPIA

Regulator perspective
Jessica Mwinyi, Medical Products Agency (MPA), Sweden

16:45 Closing remarks

Wrap up **10'**
Peter Arlett, EMA