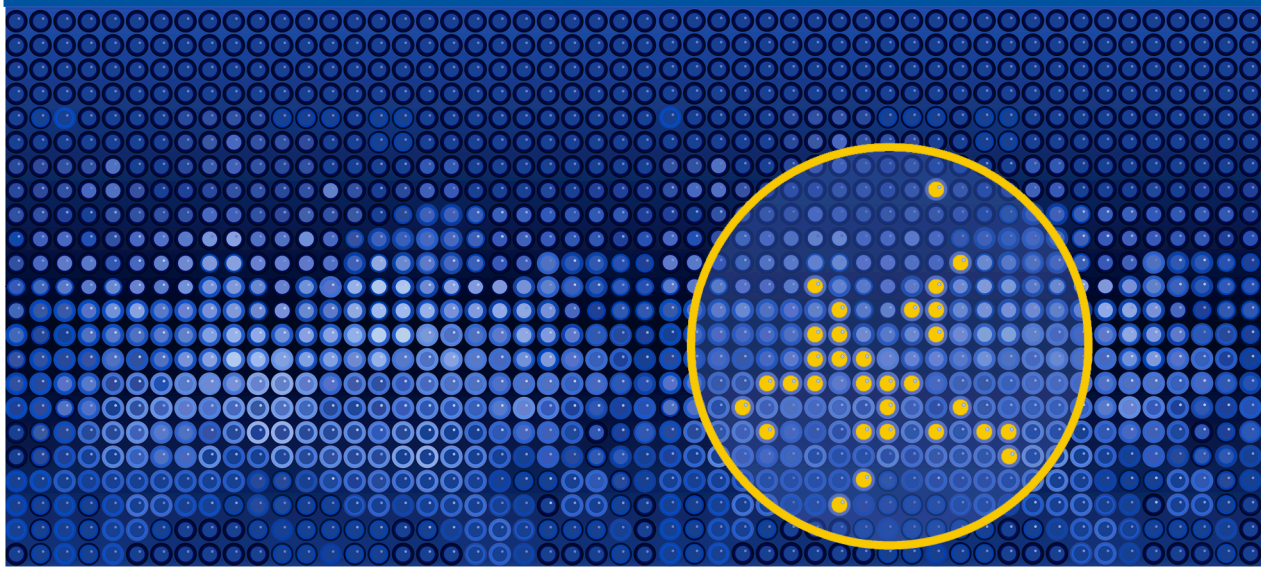
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2012
EMA/324423/2012
Human Medicines Development and Evaluation

Workshop on Pharmacogenomics: from science to clinical care

Programme

8-9 October 2012
European Medicines Agency, London, United Kingdom



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An agency of the European Union

Background

Pharmacogenomics impact on public health and opportunities for new treatment models based on prediction and prevention

Pharmacogenomics has become an actual scientific application in drug development and evaluation. A number of medicinal products based on pharmacogenomics have been developed by the pharmaceutical industry, submitted to the Agency for scientific advice or for Marketing Authorisation and are made available to the patients across Europe and globally. Pharmacogenomics is also emerging as an important tool in the evaluation of serious adverse reactions experienced in clinical care.

Objectives of the workshop

- To share international expert views on pharmacogenomic applications in clinical development, the evaluation of marketing authorisations and patient's access to medicines.
- To discuss challenges and bottlenecks.
- To identify areas for regulators and other stakeholders' joint actions.
- To serve as a training forum for senior assessors of the EU expert network.

Members of the Scientific Committee:

- Tomas Salmonson
- Krishna Prasad
- Agnes Saint Raymond
- Marisa Papaluca
- Falk Ehmann

Programme details

Monday, 8 October 2012

08:30 **Registration**

09:00 **Welcome note**

Marisa Papaluca, EMA

09:30 **Opening keynote lecture**

Genomics in science and clinical care
Frédérique Nowak, French National Cancer Institute (INCa), France

10:00 **Session 1: Pharmacogenomics: regulatory and methodological implications in early clinical development**

Chair: Krishna Prasad, CHMP-Pharmacogenomics Working Party Chair
Co-chair: Falk Ehmann, EMA

Pharmacogenomics in Rare Diseases: Development Strategy for Ivacaftor as a Therapy for Cystic Fibrosis
Federico Goodsaid, Vertex Pharmaceuticals, USA

Guideline on the use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products
Marc Maliepaard, CHMP-Pharmacogenomics Working Party member

Guideline on Clinical Pharmacogenomics:Premarketing Evaluation in Early Phase Clinical Studies + case-study
Michael Pacanowski, FDA, USA

Panel discussion (Q&A and Discussion)

11:30 **Coffee break**

11:45 **Session 2: Methodology and adaptive designs and in confirmatory clinical trials**

Chair: Robert Hemmings, CHMP-Scientific Advice Working Party Chair, EMA
Co-chair: Francesco Pignatti, EMA

Reflection paper on methodological issues associated with PG biomarkers for patients' population selection
Krishna Prasad, CHMP-Pharmacogenomics Working Party Chair

Adaptive designs
Martin Posch, University of Vienna, Austria

Evaluation & implementation challenges with prognostic/predictive genomic signatures in clinical drug development
Dr. Viswanath Devanarayan, Abbott Laboratories, UK

Panel discussion (Q&A and Discussion)

13:00 **Lunch break**

14:00 **Session 3: Post-approval pharmacogenomics: impact on Risk Management Plans and Information**

Chair: June Raine, Pharmacovigilance Risk Assessment Committee Chair
Co-chair: Isabelle Moulon, EMA

New Pharmacovigilance legislation and genomics (TBC)
Peter Arlett, EMA

Concept paper on key aspects for the use of pharmacogenomic methodologies in the pharmacovigilance evaluation of medicinal products
Qun-Ying Yue, CHMP-Pharmacogenomics Working Party and Pharmacovigilance Risk Assessment Committee member

Confirmation of a pharmacogenetic association with a rare adverse event, **Keith Johnson**, Novartis, Switzerland

Panel discussion (Q&A and Discussion)

15:30 **Closing remarks by Krishna Prasad**

16:00 **End of meeting – Day 1**

Tuesday, 9 October 2012

09:00 Opening keynote lecture

Hans Georg-Eichler, EMA

09:30 Session 4: Pharmacogenomics guided treatments in clinical care: experience from patients and health care professionals (HCPs)

Chair: David Haerry, EATG, Belgium
Co-chair: Marisa Papaluca, EMA

David Haerry, EATG, Belgium

Robert Diasio, Mayo Clinic Cancer Center, USA

Ronald van Schaik, Erasmus Medical Center, the Netherlands

Panel discussion (Q&A and Discussion)

11:00 Coffee break

11:15 Session 5: Pharmacogenomics: impact and needs from health care view point to facilitate patients' access

Chair: Tomas Salmonson, Acting CHMP Chair
Co-chair: Jane Moseley, EMA

IVDD revision
Fabio Faroulo, European Commission, Belgium

Companion diagnostics
Stuart Hogarth, Department of Social Science, Health and Medicine King's College London, UK

HTA of Companion diagnostics
Elisabeth George, National Institute for Health and Clinical Excellence (NICE), UK

Panel discussion (Q&A and Discussion)

12:45 Lunch break

13:45 Session 6: Pharmacogenomics in the global landscape: Pharmacogenetics and Ethnicity

Chair: Stephen Spielberg, FDA, USA
Co-chair: Emer Cooke, EMA

Genomics in Patients with Hispanic ancestry
Adrian Llerena, CHMP-Pharmacogenomics Working Party member

Genomics in Patients with Japanese ancestry
Yoshiaki Uyama, PMDA, Regulatory Science, Japan

Differences in strength of association across racial/ancestral groups
Steven Lewitzky, Novartis, Switzerland

Panel discussion (Q&A and Discussion)

15:15 Closing remarks by Tomas Salmonson

15:45 End of meeting – Day 2

Conference venue and secretariat

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