RISK MINIMISATION Implementation & Evaluation of EU Studies

1-DAY PRACTICAL WORKSHOP

24th March 2015 I The Royal Society of Medicine I London

For the Post-workshop 3-DAY COURSE on EU HEALTHCARE FOR PHARMACOEPIDEMIOLOGY & RISK MINIMISATION STUDIES click here

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WORKSHOP OVERVIEW

An understanding of risk minimisation is now key to the successful introduction and maintenance of drugs on the market.

This master class focuses on acquiring and applying the practical regulatory, scientific and logistical aspects of additional risk minimisation measures and their evaluation in the EU.

Learning Objectives - to understand additional risk minimisation measures from regulation to action in the EU:

- Understand the regulations and regulatory expectations
- Foresee future developments at the EMA in risk minimisation
- Proactively plan to be compliant in your company
- Appreciate how risk minimisation tools are developed
- Learn how to evaluate the effectiveness of planned and ongoing risk minimisation
- Appreciate the pitfalls and deficiencies in risk minimisation plans
- Discuss your challenges in risk minimisation with a senior regulator
- Increase effective alignment of studies with regulators
- Practice with real-life case studies and hypothetical cases
- Learn from the experience of former professionals in big pharma

WHO SHOULD ATTEND

People in European and non-European organisations involved in Risk Management, PASS studies & Risk Minimisation in Europe:

- **Drug Safety**
- **Epidemiologists**
- **Clinical Development**
- **Medical Affairs staff**
- **Regulatory Affairs staff**
- **Statisticians**

SPEAKERS

Dr. Sabine Straus, *Medicines Evaluation Board the Netherands. Dutch PRAC member. Member of the writing committee for GVP module XVI on risk minimisation*. Formerly Head of Pharmacovigilance at the Dutch Medicines Evaluation Board; Memberships of the European Medicines Agency (EMA) working parties: Member Incident Review Network (IRN) and European Risk Management Facilitation Group (ERMS).

Prof. Jeffrey Aronson, *Reader in Clinical Pharmacology, Oxford University and Honorary Consultant Physician, John Radcliffe Hospital. Member of Technology Appraisal Committee of NICE.* Former Editor-in-Chief of the British Journal of Clinical Pharmacology; President Emeritus of the British Pharmacological Society; co-inventor of the EIDOS/DoTS classification system for ADRs, *former member of the UK Medicines Commission*.

Dr. Nawab Qizilbash, *Epidemiologist & Geriatrician,* Head at OXON Epidemiology and Honorary Senior Lecturer in Pharmacoepidemiology, London School of Hygiene & Tropical Medicine; Honorary Consultant Geriatrician, Madrid; Member of Green-Templeton College, Oxford University and ENCePP nominated 'EMA Expert'. Formerly: Director of Epidemiology at GSK (1997-2005); Honorary Consultant Physician, Radcliffe Infirmary, Oxford.

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WORKSHOP PROGRAMME - *24th March 2015*

9.00 – 9.20 **Welcome and Introductions**

***Dr. Nawab Qizilbash**, Clinical Epidemiologist, OXON and London School of Hygiene & Tropical Medicine*

9.20 – 10.00 **Theoretical approach & working framework for risk minimisation**

- Prevention: susceptibility /monitoring
- Protective strategies & influencing prescribing habits
- Examples

***Professor Jeffrey Aronson**, Reader in Clinical Pharmacology, Oxford University; former Editor-in-Chief of the British Journal of Clinical Pharmacology; former member of the UK Medicines Commission*

10.00 – 12.00 **Regulatory background**

- The importance of Risk Management
- How Risk Minimisation emerges (EU additional RM vs. US REMS vs. CIOMS)

GVP regulations for risk minimization

Available tools and guidance at the EU level

- Regulatory decision on the need for aRMM
- Type and number of drugs with aRMM
- Description of aRMM tool options

***Dr. Sabine Straus**, Medicines Evaluation Board the Netherands; Dutch PRAC member; member of the writing committee for GVP module XVI on risk minimisation*

12.00 – 13.00 **Practical approach to the selection and development of aRMM – pre *and post approval***

- Assessment of the need for aRMM within EU-RMPs
- Selection of aRMM
- Development of aRMM
- Implementation of aRMM
- Industry examples

***Dr. Nawab Qizilbash**, Clinical Epidemiologist, OXON and London School of Hygiene & Tropical Medicine*

13.00 Lunch

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WORKSHOP PROGRAMME - *24th March 2015*

14.00 – 15.00 **Practical approach to the evaluation of the effectiveness of aRMM**

- Study designs
- Data sources
- Industry examples & issues

***Dr. Nawab Qizilbash**, Clinical Epidemiologist,OXON and London School of Hygiene & Tropical Medicine*

15.00 – 15.45 **Review of the results of additional risk minimisation measures**

***Dr. Sabine Straus**, Medicines Evaluation Board the Netherands; Dutch PRAC member; member of the writing committee for GVP module XVI on risk minimisation*

15.45 – 16.45 **Challenges and ways forward: How regulators may react to various additional risk minimisation measures and studies – *hypothetical scenarios***

***Dr. Sabine Straus**, Medicines Evaluation Board the Netherands; Dutch PRAC member; member of the writing committee for GVP module XVI on risk minimisation*

***Professor Jeffrey Aronson**, Reader in Clinical Pharmacology, Oxford University;*

***Dr. Nawab Qizilbash**, Clinical Epidemiologist, OXON and London School of Hygiene & Tropical Medicine*

16.45 – 17.00 **Summary**

***Dr. Nawab Qizilbash**, Clinical Epidemiologist, OXON and London School of Hygiene & Tropical Medicine*

17.00 End of Workshop

VENUE

The Royal Society of Medicine
Chandos House
2 Queen Anne Street
London W1G 9LQ

WORKSHOP REGISTRATION FORM

Please complete this registration form to express interest in attending one of our courses or send your details to **info@oxonepi.com**. Being workshops the number of attendees is **limited**. Therefore, we will first confirm your place and only then will we request payment of the registration fee.

Contact Information

First name*: _____

Last Name*: _____

Company/Organisation*: _____

Position*: _____

Address: _____

Country: _____

Contact Phone No.: _____

E-mail*: _____

* *Mandatory fields*

Prices *(includes social event, lunch & refreshments)*

☐ **Risk Minimisation in the European Union - Practical Workshop (24th March 2015)**

- ○ Normal rate for pharmaceutical company staff: **£290** (20% UK VAT not included)
- ○ For people who work entirely in non-commercial organisations: **£250** (20% UK VAT not included)

☐ **European Healthcare for Pharmacoepidemiology and Risk Minimisation - Course (25th – 27th March 2015) - STARTS THE DAY AFTER THE WORKSHOP IN THE SAME VENUE**

- ○ Normal rate for pharmaceutical company staff: **£1,450** (20% UK VAT not included)
- ○ For people who work entirely in non-commercial organisations: **£1,250** (20% UK VAT not included)

Accomodation

Accomodation in the Conference Venue is limited, so **book early!**

Tel: +44 (0) 020 7290 3820
Email: chandos.house@rsm.ac.uk

WAYS TO REGISTER

First download this PDF form, complete the form electronically and then click the 'submit form' button to send automatically to info@oxonepi.com

OR print and fax to +34 913 597 312

OR just e-mail: info@oxonepi.com

Confirmation of registration will be made by e-mail within 1 working day

Cancellation

Cancellations must be received in writing.

If you have NOT received registration confirmation within 2 working days of registering please call +34 913 459 395

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