Implementation & Evaluation of RISK MINIMISATION in Europe

3rd ANNUAL 1-DAY PRACTICAL WORKSHOP

18th March 2016 I The Royal Society of Medicine I London

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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**

VENUE

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

SPEAKERS

Dr. Sabine Straus, *Medicines Evaluation Board the Netherlands. PRAC member and Rapporteur of the GVP Module XVI on risk minimisation.* Former Head of Pharmacovigilance at the Dutch Medicines Evaluation Board; Memberships of the 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 EI DOS/DoTS classification system for ADRs, *former member of the UK Medicines Commission*.

Dr. Annalisa Rubino, *Director of Risk Management Epidemiology, OXON.* Former EMA Rapporteur of GVP XVI on Risk Minimisation; Former Member of the EMA Risk Management team (2010 2015).

Dr. Rachel Sobel, *Senior Director and a Group Lead for Global Innovative Pharmaceuticals for Epidemiology at Pfizer Inc. in New York, NY.*

Dr. Lesley Wise, *Vice President of Global PV Risk Management and Pharmacoepidemiology at Takeda.*

Dr. Nawab Qizilbash, *Epidemiologist & Geriatrician, Head at OXON Epidemiology and Honorary Senior Lectu rer 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 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 (18th March 2016)**

- ◯ Normal rate for pharmaceutical company staff: **£350** (20% UK VAT not included)
- ◯ For people who work entirely in non-commercial organisations: **£300** (20% UK VAT not included)

☐ **European Healthcare for Pharmacoepidemiology and Risk Minimisation - Course (15th – 17th March 2016) - BEFORE 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 +34 913 450 677

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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