4th ANNUAL COURSE in European HEALTHCARE for PHARMACOEPIDEMIOLOGY & RISK MINIMISATION Studies

15th - 17th March 2016 I The Royal Society of Medicine

TOPICS for each country

- Understanding Heath Care for Observational Studies
- Secondary Data Studies
- Field Studies (including patient registries, retrospective chart review studies & surveys)
- Practical designing and planning field & database studies

EU multi-country TOPICS

- EU multi-country pharmacoepidemiological database studies
- EU multi-country pregnancy registries
- EU Risk Minimisation studies

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COURSE OVERVIEW

An understanding of the health care system and how medicine is practiced is essential to the design and planning of successful pharmacoepidemiological (PE) and risk minimisation (RM) studies. The course focuses on acquiring this practical knowledge and applying it to PE and RM studies.

Native, European, pharmacoepidemiologists and clinicians experienced in PE and RM studies in each of the 'big 5' EU countries and, collectively, the 'small 5' countries (database/national registry-rich countries of Denmark, Finland, Norway, Sweden and Holland) will make presentations, lead practicals and provide ample time to respond to questions based on their experience of different study designs, therapeutic areas and age groups, with drugs and vaccines.

Learning Objectives - for conducting PE and RM studies in different therapeutic areas for each of the listed EU countries – to become familiar with:

For each of the countries:

Part I: Understanding Heath Care for Observational Studies

- Key demography, culture, politics and history
- Structure of health care (including private health care)
- Primary care / Secondary care
- Patient clinical management flows
- Country-specific patient confidentiality, consent and data protection
- Study approval procedures – theory and practice
- Country-specific adverse event reporting obligations
- Medical societies, patient groups and health insurance
- Payments for research (to investigators, societies, database providers, etc.)

Part II: Secondary Data Studies

- Primary care
- Secondary care
- Drug utilisation
- Strengths, limitations and challenges for different study designs and therapeutic areas

Part III: Field Studies

- Prospective studies and registries
- Retrospective data collection studies
- Cross-sectional studies
- Strengths, limitations and challenges for different study designs and therapeutic areas

Part IV: Practical designing and planning field and database studies

EU multi-country pharmacoepidemiological database studies

EU Risk Minimisation studies

EU multi-country pregnancy registries

WHO SHOULD ATTEND

People in European and non European organisations involved in the conduct of observational studies in Europe:

- **Epidemiologists**
- **Drug Safety**
- **Clinical Development**
- **Scientific leads**
- **Health Economists**
- **Statisticians**
- **Medical Affairs staff**

WHAT PAST ATTENDEES SAY

"Excellent overview of EU systems/ opportunities for studies. Acquired knowledge seems applicable (i.e. not too theoretical). Networking, high level of expertise of faculty"

"Would recommend to colleagues at epidemiology and safety department. Yes, good overview of the various health systems in EU and understanding of limitations to perform observational studies in EU"

Meaningful and relevant exploration of EU countries´systems and approached to conducting observational research"

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COURSE SPEAKERS & TOPICS

COUNTRIES

FRANCE

***Prof. Nicholas Moore**, Clinical Pharmacologist/ Pharmacoepidemiologist, University of Bordeaux*

GERMANY

***Prof. Edeltraut Garbe,** Clinical Epidemiologist, BIPS, University of Bremen*

ITALY

***Prof. Carlo Giaquinto,** Clinical Epidemiologist, University of Padova & Pedianet*

'SMALL 5'

***Prof. Ulf Bergman**, Clinical Pharmacologist/ Pharmacoepidemiologist, Karolinska Institute, Stockholm, Sweden*

***Dr. Vera Ehrenstein**, Database Epidemiologist, University of Aarhus, Denmark*

SPAIN

***Dr. Diego Macías**, Pharmacoepidemiology and Pharmacovigilance Division. The Spanish Agency of Medicines and Medical Devices, Madrid*

***Dr. Lorenzo Dominguez**, Medical Epidemiologist, OXON, Madrid*

***Dr. Gema Requena**, Pharmacoepidemiologist, OXON, London*

UNITED KINGDOM

***Prof. Tom Macdonald,** Clinical Pharmacologist/ Pharmacoepidemiologist, University of Dundee*

***Andrew Maguire,** Database Epidemiologist, OXON, London*

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

EU RISK MINIMISATION STUDIES

***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)*

EU MULTI-COUNTRY PHARMACOEPIDEMIOLOGICAL DATABASE STUDIES

***Prof. Miriam Sturkenboom**, Pharmacoepidemiologist, Erasmus University, Rotterdam, Holland; EU-ADR, GRIP and VAESCO European Vaccine Safety Datalink*

EU MULTI-COUNTRY PREGNANCY REGISTRIES

***Prof. Helen Dolk,** Epidemiology & Health Services Research, Belfast, UK; Director of WHO Collaborating Centre for Epidemiologic Surveillance of Congenital Abnormalities*

VENUE

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

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COURSE 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)*

☐ **European Healthcare for Pharmacoepidemiology and Risk Minimisation - Course (15th – 17th March 2016)**

- ◯ 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)

☐ **Risk Minimisation in EUROPE - Practical Workshop (18th March 2016) - AFTER THE COURSE IN THE SAME VENUE**

- ◯ 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)

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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