Confirmed Faculty

UK

Prof. Tom MacDonald, *Clinical Epidemiologist, University of Dundee*

Andrew Maguire, *Database Epidemiologist, OXON, London*

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

France

Prof. Eric Van Ganse, *Clinical Epidemiologist, University of Lyon*

Germany

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

Italy

Prof. Carlo Giaquinto, *Clinical Epidemiologist, Dep. of Paediatrics and Pedianet, Padova*

Prof. Adriana Ceci, *Regulatory Science, Drug Registry & Paediatric Research expert 'Gianni Benzi' Pharmacological Research Foundation President, Bari*

Spain

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

Dr. Lorenzo Domínguez, *Epidemiology Project Manager, OXON, Madrid*

Ignacio Mendez, *Outcomes Researcher, OXON, Madrid*

'Small 5' Countries: Denmark, Finland, Norway, Sweden & Holland

Prof. Ulf Bergman, *Clinical Epidemiologist, Karolinska Institutet, Sweden*

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

Prof. Miriam Sturkenboom, *Epidemiologist, Erasmus University, Holland*

EU Risk Minimisation Studies

Dr. Sabine Straus, *European Medicines Agency PRAC member*

Further details

Who should attend **-** People in European and non-European organisations involved in the conduct of observational studies in Europe: Epidemiologists, Drug Safety, Scientific leads, Medical Affairs staff, and others.

Language **-** English

Registration: Places will be limited to permit adequate time for discussion and feedback during the presentations and practicals.

Further details and registration at:

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European HEALTHCARE for PHARMACOEPIDEMIOLOGY & RISK MINIMISATION Studies

3-DAY COURSE

19th - 21st March 2014

The Royal Society of Medicine, London

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 in different therapeutic areas.

Native, European, pharmacoepidemiologists, clinicians and project managers 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 the:

- Challenges, viability, strengths and weaknesses of conducting different types of studies
- Data sources that exist for conducting different types of studies
- Practical aspects of designing and planning field and database studies:
  - **Appreciate** - typical patient clinical management flows
  - **Describe** - the health care system, including physician, medical societies, patients and other relevant factors to conducting studies
  - **Take away** - a list of data sources and resources relevant to the practical conduct of studies
  - **Practice** – designing and planning studies

Topics at a glance

Half Day for each ´Big 5´ country and, collectively, ´Small 5´ countries:

France, Germany, Italy, Spain, UK & 'Small 5´
(Denmark, Finland, Norway, Sweden & Holland)

Part I: Understanding Health 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.)
- Internet accessibility

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 (including patient registries)

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

Part V: Practical - Designing and planning a pharmacoepidemiological study

And **EU multi-country pharmacoepidemiological database studies**

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