2nd COURSE

EUROPEAN HEALTH CARE for PHARMACOEPIDEMIOLOGY

& RISK MINIMISATION

3-DAY WORKSHOP MASTER CLASS

19-21 March 2014

The Royal Society of Medicine, London, UK

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, 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 in each of the key countries

WHO SHOULD ATTEND - People in European and non-European organisations involved in the conduct of observational studies in Europe: Epidemiologists, Drug Safety specialists Scientific Leads, Medical Affairs staff and others.

LANGUAGE - English

VENUE - The Royal Society of Medicine, 2 Queen Anne Street, London W1G 9LQ

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

ACCOMODATION – Rooms will be available at The Royal Society of Medicine, Chandos House, 2 Queen Anne Street, London W1G 9LQ.

Tel: +44 (0) 020 7290 3820

Email: chandos.house@rsm.ac.uk

PROGRAMME

19th March 2013: Day 1

9.00 – 9.10	**Welcome and Introductions** ***Dr. Nawab Qizilbash**, Clinical Epidemiologist, OXON and London School of Hygiene & Tropical Medicine*
09.10 -12.10 (with break for coffee/tea)	**ITALY** ***Professor Carlo Giaquinto**, Clinical Epidemiologist, University of Padova & Pedianet;* ***Professor Adriana Ceci**, Regulatory Science, Drug Registry & Paediatric Research expert 'Gianni Benzi' Pharmacological Research Foundation President, Bari* **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.) • 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** • Primary care • Secondary care • Strengths, limitations and challenges for different study designs and therapeutic areas **Part IV: Practical: Designing & planning pharmacoepidemiological studies**
12:10 – 13:00	**EU Risk Minimisation Studies** ***Dr. Sabine Straus**, Pharmacovigilance Risk Assessment Committee (PRAC) member*
13.00 -14.00	**Lunch**
14.00 - 14.45	**Conducting EU multi-country pharmaco-epidemiological database studies** ***Professor Miriam Sturkenboom**, Pharmacoepidemiologist, Erasmus University, Rotterdam, Holland*
14.45 -18.00 (with break for coffee/tea)	**' Small 5' Countries: Denmark, Sweden, Finland, Norway & Holland** ***Professor Ulf Bergman**, Clinical Pharmacologist/Epidemiologist, Karolinska Institute, Stockholm, Sweden & **Dr Vera Ehrenstein**, Database Epidemiologist, University of Aarhus, Denmark*

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.)
- 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

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

Part IV: Practical: Designing & planning pharmacoepidemiological studies

18.00	**End of day 1**

20th March 2013: Day 2

9.00 - 9.05	**Welcome to Day 2**
9.05 – 12.30 (with break for coffee/tea)	**FRANCE** ***Professor Eric Van Ganse**, Clinical Epidemiologist, University of Lyon, France* **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.) • 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** • Primary care • Secondary care • Strengths, limitations and challenges for different study designs and therapeutic areas **Part IV: Practical: Designing & planning pharmacoepidemiological studies**
12.30 – 13.30	**Lunch**
13.30 – 17.00 (with break for coffee/tea)	**UK** ***Professor Tom Macdonald**, Clinical Pharmacologist/Epidemiologist, University of Dundee; **Andrew Maguire**, Database Epidemiologist, OXON, London; **Dr. Nawab Qizilbash**, Geriatrician and Epidemiologist, OXON and London School of Hygiene & Tropical Medicine* **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.) • 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** • Primary care • Secondary care • Strengths, limitations and challenges for different study designs and therapeutic areas **Part IV: Practical: Designing & planning pharmacoepidemiological studies**
17.00	**End of Day 2**

21st March 2013: Day 3

8.30 - 8.35	**Welcome to Day 3**
8.35 - 12.00 (with break for coffee/tea)	**GERMANY** ***Professor Edeltraut Garbe**, Clinical Epidemiologist, BIPS, University of Bremen* **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.) • 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** • Primary care • Secondary care • Strengths, limitations and challenges for different study designs and therapeutic areas **Part IV: Practical: Designing & planning pharmacoepidemiological studies**
12.00 – 12.45	**Lunch**
12.45 – 16.00 (with break for coffee/tea)	**SPAIN** ***Dr. Diego Macías**, Pharmacoepidemiology and Pharmacovigilance Division. The Spanish Agency of Medicines and Medical Devices, Madrid, Spain; **Dr. Lorenzo Dominguez**, Epidemiology Project Manager; & **Ignacio Mendez**, Outcomes Researcher, OXON, Madrid* **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.) • 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

- Primary care
- Secondary care
- Role of medical societies & patient groups
- Strengths, limitations and challenges for different study designs and therapeutic areas

Part IV: Practical: Designing and planning pharmacoepidemiological studies

16.00	**End of Workshop**

The timing of individual presentations and named speakers may be subject to change