

INTRODUCTION TO PHARMACOEPIDEMIOLOGY

Southampton area

4 - 5 JULY 2012

PROGRAMME – 4 JULY 2012

Pharmacoepidemiology – the Basics

- 0830 - 0900** **Registration for delegates**
- 0900 - 0915** **Welcome and introduction to the course**
Housekeeping ■ Introduction to the Faculty ■ Aims of the course
- 0915 - 0945** **What is epidemiology and what do we use it for? [DSS 1]**
Teaching objectives: To familiarise course members with applications of epidemiological technique and application, and to understand the basic difference between epidemiological tools and other scientific evaluation.
■ Definitions, scope and applications of epidemiology ■ Population perspectives and disease burden ■ Prevalence and Incidence ■ Use of observational data ■ Prevention
- 0945 - 1015** **What is pharmacoepidemiology and what do we use it for? [DSS 1]**
Teaching objectives: To bring any course members who are not familiar with applications of epidemiological technique and application the chance to understand the basic difference between epidemiological tools and other scientific evaluation.
■ Definitions, historical background, scope (principle of scientific method) and applications of pharmacoepidemiology
- 1015 - 1030** **Coffee**
- 1030 – 1115** **Basics concepts in pharmacoepidemiology [DSS 6]**
Teaching objectives: To give the course members a basic grounding in pharmacoepidemiological conceptual skills and how the tools are used for evaluating risk and risk benefit.
■ Safety ■ Risk and related concepts ■ Understanding statistical measures in pharmacoepidemiology ■ Risk / benefit balance ■ Association ■ Bias and confounding ■ Causation
- 1115 - 1120** **Introduction to workshop on causation**
- 1120 - 1220** **Workshop on causation [DSS 5]**
Teaching objectives: To increase delegates' understanding of how causality is determined from pharmacoepidemiological data using information of different types derived from three real examples of potentially serious adverse events associated with medicines.
- 1220 – 1250** **Feedback on worked examples**
- 1250 – 1350** **Lunch**
- 1350 - 1435** **Data resources for pharmacoepidemiology [DSS 5]**
Teaching objectives: To enable course members to fully understand where they might search for data once a potential signal has been recognised.

▪ *Broad overview of worldwide data resources* ▪ *Strengths and limitations of principal databases* ▪ *Use of registries*

1435 – 1520

Study designs and tools [DSS 5]

Teaching objectives: To give the course members a basic grounding in pharmacoepidemiological study design and how the tools are used for evaluating risk and risk benefit.

▪ *Hypothesis generation and testing* ▪ *Case reports and case series* ▪ *Principles of study design* ▪ *Cohort studies* ▪ *Case-control studies* ▪ *Interventional studies*
▪ *Systematic reviews*

1520 – 1535

Tea

1535 – 1630

Interactive introduction to common methods used in the analysis of pharmacoepidemiological data [Part I]

Teaching objectives: To introduce course members to common techniques of analysis used to aid interpretation of pharmacoepidemiological investigations

▪ *Descriptive statistics* ▪ *calculating point estimates and confidence intervals*
▪ *Influence of confounding, error and biases on results* ▪ *Methods to control for confounding* ▪ *Statistical Modelling*

1630 – 1715

Pharmacoepidemiology and signal detection [DSS 4]

Teaching objectives: To introduce course members to signal detection and how it is used.

▪ *What is a signal?* ▪ *How are signals detected?* ▪ *Statistical approaches to signal detection*

1715 - 1745

HMT/PMST/Postgraduate Candidates ONLY are requested to meet Prof Saad Shakir to discuss the pre-course assignment for this course

1900

Complimentary course dinner

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Practical application of pharmacoepidemiology

- 0845 - 0900** **Registration for delegates**
- 0900 - 0930** **Interactive introduction to common methods used in the analysis of pharmacoepidemiological data [Part II]**
Teaching objectives: To introduce course members to common techniques of analysis used to aid interpretation of pharmacoepidemiological investigations
▪ *Descriptive statistics* ▪ *calculating point estimates and confidence intervals*
▪ *Influence of confounding, error and biases on results* ▪ *Methods to control for confounding* ▪ *Statistical Modelling*
- 0930 – 1000** **Survival methods in pharmacoepidemiology**
Teaching objectives: to explore how survival (time to onset) methods are used in medical studies.
▪ *Key terms and concepts* ▪ *Survival analysis methods* ▪ *Graphing survival data (Kaplan-Meier)*
- 1000 – 1030** **What is meta-analysis?**
Teaching objectives: To give the course members a basic understanding of meta-analysis in pharmacoepidemiology
- 1030 – 1045** **Coffee**
- 1045 – 1115** **Good Pharmacoepidemiology Practices**
Teaching objectives: To give the course members an overview of current initiatives and expectations pertaining to the planning, conduct, and evaluation of pharmacoepidemiologic research
- 1115 – 1125** **Introduction to workshop on interpretation [DSS 5]**
Teaching objectives: To summarise the skills and approach required to interpreting pharmacoepidemiological studies in preparation for the following workshop
- 1125 - 1240** **Workshop on interpretation of pharmacoepidemiological data [DSS 5]**
Teaching objectives: To give course members a chance to interpret published studies and critically evaluate the conclusions. Three examples will be used based on differing study designs.
- 1240 - 1300** **Feedback from the workshop**
- 1300 - 1400** **Lunch**
- 1400 – 1430** **How can pharmacoepidemiology support risk management? [DSS 5 & 10]**

Teaching objectives: To help participants understand how to incorporate pharmacoepidemiology into risk management planning.

▪ *Practical implications of ICH E2E* ▪ *Tailoring the approach* ▪ *Meeting the requirements of regulators* ▪ *Pitfalls to avoid*

1430 – 1500

Using pharmacoepidemiology to demonstrate safety and manage risks [DSS 5 & 10]

Teaching objectives: To enable participants to gain insight into the potential uses and value of pharmacoepidemiological data in the early post-marketing period.

▪ *Concepts underpinning risk management planning* ▪ *Uses of pharmacoepidemiological data* ▪ *Evaluation of risk minimisation measures*

1500 – 1515

Tea

1515 - 1525

Introduction to risk management planning workshop [DSS 5]

1525 – 1625

Workshop: Pharmacoepidemiology as a tool for risk management planning [DSS 5]

Teaching objectives: To provide delegates with an opportunity to define the key elements of a risk management plan using practical examples.

1625 – 1655

Feedback from the workshop

1655 - 1715

Summary of key course messages and where to find out more

Teaching objectives: To summarise the key take-home messages from the course and provide delegates with information on how and where to learn more about pharmacoepidemiology.

▪ *Key messages* ▪ *Educational resources and opportunities*

1720

Close of course