

DEVELOP
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POTENTIAL

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KNOWLEDGE



Drug Safety Research Unit

Introduction to Pharmacoepidemiology

Solent Hotel, Whiteley near Fareham

1 – 2 April 2020

Wednesday 1 April

Course objective: To familiarise course members with epidemiological techniques and applications, and to help them understand the basic differences between epidemiological tools and other scientific evaluation.

0815 - 0845 Registration for delegates

0845 - 0900 Welcome and introduction to the course

0900 – 0945 What are epidemiology and pharmacoepidemiology and what do we use them for?

◇ Definitions, scope and applications of pharmacoepidemiology ◇ Population perspectives and disease burden ◇ Use of observational data ◇ Prevention

0945 - 1100 Basic concepts in pharmacoepidemiology

◇ Safety ◇ Risk and related concepts ◇ Understanding statistical measures in pharmacoepidemiology ◇ Risk / benefit balance ◇ Association ◇ Bias and confounding ◇ Causation

Learning objectives:

- To acquire a basic grounding in pharmacoepidemiological conceptual skills and how the tools are used for evaluating risk and risk benefit.

1100 - 1115 Coffee

1115 - 1200 Study designs and tools

◇ Hypothesis generation and testing ◇ Case reports and case series ◇ Principles of study design ◇ Cohort studies ◇ Case-control studies ◇ Interventional studies

Learning objectives:

To acquire a basic grounding in pharmacoepidemiological study design and how the tools are used for evaluating risk and risk benefit.

1200 - 1300 PASS, PAES and risk management

◇ Practical implications of ICHE2E ◇ Tailoring the approach ◇ Meeting the requirements of regulators ◇ Pitfalls to avoid ◇ ENCePP E-Register of Studies

Learning objectives:

Book your place here: <https://www.dsru.org/education-training/>
Contact us on EandT@dsru.org or 023 8040 8600

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In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

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- To learn how pharmacoepidemiological methods are used in Post-authorisation Safety Studies (PASS) and Post-authorisation Efficacy Studies (PAES) in the UK and EU.
- To understand how to incorporate pharmacoepidemiology into risk management planning.

1300 - 1345 **Lunch**

1345 - 1350 **Introduction to methodology workshop**

1350 - 1445 **Workshop on methodology**

Learning objectives:

- To be able to identify key features of commonly used pharmacoepidemiological study designs and become familiar with the methods used for measurement of exposure and outcomes.
- To understand how study populations are selected.

1445 – 1530 **Interactive introduction to key measures of frequency**

◇ Key terms and concepts ◇ Descriptive statistics ◇ Calculating measures of frequency

Learning objectives:

- To learn common techniques of analysis used to aid interpretation of pharmacoepidemiological investigations

1530 - 1545 **Coffee**

1545 - 1630 **Interactive introduction to measures of impact and effect**

◇ Key terms and concepts ◇ Calculating measures of impact and measures of effect (risk ratios, odds ratios and hazard ratios)

Learning objectives:

- To learn common techniques of analysis used to aid interpretation of pharmacoepidemiological investigations

1630 - 1645 **Discussion**

1645 **Close of day one**

1645 - 1730 **PMST trainees and Postgraduate Students ONLY are requested to meet the Assessor to discuss their pre-course assignment for this course**

1730 - 1740 **PMST trainees and Postgraduate Students ONLY to discuss post-course assignment with Course Leader, Dr Vicki Osborne**

1740 - 1815 **Complimentary networking drinks reception**

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Thursday 4 April

0830 – 0840 Registration

0830 - 0840 **Postgraduate in Pharmacovigilance students only**
Student meeting

0840 - 0845 Introduction to day 2 and recap of day 1

0845 - 0930 Data resources for pharmacoepidemiology

◇ Broad overview of worldwide data resources ◇ Strengths and limitations of databases ◇
Choosing an appropriate data resource ◇ ENCePP

Learning objectives:

- To fully understand where you might search for data once a potential signal has been recognised.

0930 - 1015 Interactive introduction to data sampling issues

◇ Uncertainty and variation

Learning objectives:

- To become familiar with underlying data sampling issues

1015 – 1030 Discussion

1030 - 1045 Coffee

1045 - 1130 Interactive introduction to bias, confounding and interaction

◇ Bias, interaction and confounding

Learning objectives:

- To become familiar with underlying data sampling and study design issues

1130 – 1140 Introduction to following workshop

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1140 – 1225 Workshop on interpretation of pharmacoepidemiological data

Learning objectives:

- To interpret published studies and critically evaluate the conclusions.

1225 - 1315 Lunch

1315 - 1400 Introduction to systematic reviews and meta-analysis [DSS 3]

◇ Search strategies ◇ Synthesising data ◇ Interpreting results ◇ Assessing risk of bias and publication bias

Learning objectives:

- To obtain an overview of systematic reviews and meta-analyses

1400 - 1405 Introduction to workshop on causation

1405 - 1445 Workshop on causation

Learning objectives:

- To increase your understanding of how causality is determined from pharmacoepidemiological data using information of different types derived from two real examples of potentially serious adverse events associated with medicines.

1445 - 1500 Coffee

1500 - 1510 Introduction to following workshop

1510 - 1545 Workshop: Pharmacoepidemiology as a tool for risk management planning

Learning objectives:

- To define the key elements of a risk management plan using practical examples.

1545 – 1600 Summing up and final questions

1600 Close of meeting

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