

DEVELOP
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Drug Safety Research Unit

Introduction to Pharmacoepidemiology

Hybrid event: Solent Hotel, Whiteley, Fareham and Online

1 - 2 November 2023

Wednesday 1 November

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.

0830 - 0845 (GMT) Registration

0845 - 0900 Welcome and introduction to the course

0900 - 0930 What is epidemiology and what is pharmacoepidemiology?

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

0930 - 0935 Comfort break

0935 - 1035 Basic concepts in pharmacoepidemiology

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

Learning objectives:

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

1035 - 1050 Coffee break

1050 - 1120 Causality – Bradford Hill Criteria

1120 - 1125 Comfort break

1125 - 1210 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.

1210 - 1215 Comfort break

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

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1215 - 1300 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.

1300 - 1345 Lunch break

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 - 1450 Comfort break

1450 - 1530 Interactive introduction to measures of disease 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 break

1545 - 1645 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:

- 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.

1645 - 1700 Question & Answer session

1700 Close of day one

1700 - 1800 PMST trainees and Postgraduate Students ONLY are requested to meet the Assessor to discuss their pre-course assignment for this course

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1 - 2 November 2023

Thursday 2 November

0845 - 0900
(GMT)

Meeting room open

0900 - 0905

Introduction to day 2 and recap of day 1

0905 - 1005

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

1005 - 1015

Comfort break

1015 - 1100

Interactive introduction to data sampling issues

◇ Uncertainty and variation

Learning objectives:

- To become familiar with underlying data sampling issues

1100 - 1115

Question and answer session

1115 - 1130

Coffee break

1130 - 1140

Introduction to interpretation of pharmacoepidemiological data workshop

1140 - 1230

Workshop on interpretation of pharmacoepidemiological data

Learning objectives:

- To interpret published studies and critically evaluate the conclusions.

1230 - 1315

Lunch break

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:

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

1400 - 1405 **Comfort break**

1405 - 1410 **Introduction to causation workshop**

1410 - 1450 **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.

1450 - 1505 **Coffee break**

1505 - 1515 **Introduction to risk management planning workshop**

1515 - 1555 **Workshop: Pharmacoepidemiology as a tool for risk management planning**

Learning objectives:

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

1555 - 1615 **Summing up and final questions**

1615 **Close of meeting**

1615 - 1630 **PMST trainees and Postgraduate Students**
Student meeting to discuss any questions regarding the post-course assignment

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