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Drug Safety Research Unit

# Introduction to Pharmacoepidemiology

Solent Hotel, Whiteley near Fareham

**30 – 31 October 2019**

**Chairperson: Dr Vicki Osborne**

**Wednesday 30 October**

**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.

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| **0815 - 0845** | **Registration for delegates** |
| **0845 - 0900** | **Welcome and introduction to the course**<br>Dr Vicki Osborne, Drug Safety Research Unit |
| **0900 – 0945** | **What is epidemiology and what is pharmacoepidemiology?**<br>  <br>Dr Vicki Osborne, Drug Safety Research Unit<br><br>*◊ Definitions, scope and applications of pharmacoepidemiology ◊ Population perspectives and disease burden ◊ Use of observational data ◊ Prevention* |
| **0945 - 1045** | **Basic concepts in pharmacoepidemiology**<br>  <br>Prof Saad Shakir, Drug Safety Research Unit<br><br>*◊ Safety ◊ Risk and related concepts ◊ Understanding statistical measures in pharmacoepidemiology ◊ Risk / benefit balance ◊ Association ◊ Bias and confounding ◊ Causation*<br><br>**Learning objectives:**<br>• To acquire a basic grounding in pharmacoepidemiological conceptual skills and how the tools are used for evaluating risk and risk benefit. |
| **1045 - 1100** | **Coffee** |
| **1100 - 1145** | **Study designs and tools**<br>Prof Saad Shakir, Drug Safety Research Unit<br><br>*◊ Hypothesis generation and testing ◊ Case reports and case series ◊ Principles of study design ◊ Cohort studies ◊ Case-control studies ◊ Interventional studies*<br><br>**Learning objectives:**<br>To acquire a basic grounding in pharmacoepidemiological study design and how the tools are used for evaluating risk and risk benefit. |

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| **1145 - 1230** | **Data resources for pharmacoepidemiology**<br>Dr Vicki Osborne, Drug Safety Research Unit<br><br>*◊Broad overview of worldwide data resources ◊Strengths and limitations of databases ◊ Choosing an appropriate data resource ◊ENCePP*<br><br>**Learning objectives:**<br>• To fully understand where you might search for data once a potential signal has been recognised. |
| **1230 - 1315** | **Lunch** |
| **1315 - 1320** | **Introduction to methodology workshop**<br>Dr Debabrata Roy, Drug Safety Research Unit |
| **1320 - 1415** | **Workshop on methodology**<br>Facilitators: Debabrata Roy and Sandeep Dhanda<br><br>**Learning objectives:**<br>• 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.<br>• To understand how study populations are selected. |
| **1415 – 1445** | **Interactive introduction to key measures of frequency**<br>  <br>Dr Debabrata Roy, Drug Safety Research Unit<br><br>*◊Key terms and concepts ◊Descriptive statistics ◊Calculating measures of frequency*<br><br>**Learning objectives:**<br>• To learn common techniques of analysis used to aid interpretation of pharmacoepidemiological investigations |
| **1445 - 1500** | **Coffee** |
| **1500 - 1600** | **PASS, PAES and risk management**<br>Prof Saad Shakir, Drug Safety Research Unit<br><br>*◊Practical implications of ICHE2E ◊Tailoring the approach ◊Meeting the requirements of regulators ◊Pitfalls to avoid ◊ENCePP E-Register of Studies*<br><br>**Learning objectives:**<br>• To learn how pharmacoepidemiological methods are used in Post-authorisation Safety Studies (PASS) and Post-authorisation Efficacy Studies (PAES) in the UK and EU.<br>• To understand how to incorporate pharmacoepidemiology into risk management planning. |
| **1600 - 1630** | **Question & Answer session**<br>Led by Vicki Osborne, Drug Safety Research Unit |
| **1630** | **Close of day one** |

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| **1630 - 1715** | **PMST trainees and Postgraduate Students** ONLY are requested to meet the Assessor (Dr Vicki Osborne) to discuss their pre-course assignment for this course |
| **1715 - 1745** | **Complimentary networking drinks reception** |

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**Thursday 31 October**

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| **0830 – 0840** | **Registration** |
| **0845 - 0855** | **Postgraduate in Pharmacovigilance students only**<br>Student meeting |
| **0855 - 0900** | **Introduction to day 2 and recap of day 1**<br>Dr Vicki Osborne, Drug Safety Research Unit |
| **0900 – 0945** | **Interactive introduction to measures of impact and effect**<br>  <br>Dr Sandeep Dhanda, Drug Safety Research Unit<br><br>◊ *Key terms and concepts* ◊ *Calculating measures of impact and measures of effect (risk ratios, odds ratios and hazard ratios)*<br><br>**Learning objectives:**<br>• To learn common techniques of analysis used to aid interpretation of pharmacoepidemiological investigations |
| **0945 - 1030** | **Interactive introduction to data sampling issues**<br>  <br>Dr Debabrata Roy, Drug Safety Research Unit<br><br>◊ *Uncertainty and variation*<br><br>**Learning objectives:**<br>• To become familiar with underlying data sampling issues<br>• Debs to review slides as some of the answers to the turning point questions are already on the slides |
| **1030 - 1045** | **Question and answer session** |
| **1045 - 1100** | **Coffee** |
| **1100 - 1145** | **Interactive introduction to bias, confounding and interaction**<br>Dr Debabrata Roy, Drug Safety Research Unit<br><br>◊ *Bias, interaction and confounding*<br>**Learning objectives:**<br>• To become familiar with underlying data sampling and study design issues |

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| **1145 - 1155** | **Introduction to following workshop**<br>Mrs Lorna Hazell, Drug Safety Research Unit |
| **1155 - 1240** | **Workshop on interpretation of pharmacoepidemiological data**<br>Facilitators: Lorna Hazell and Debabrata Roy<br><br>**Learning objectives:**<br>• To interpret published studies and critically evaluate the conclusions. |
| **1240 - 1330** | **Lunch** |
| **1330 - 1415** | **Introduction to systematic reviews and meta-analysis [DSS 3]**<br>  <br>Mrs Lorna Hazell, Drug Safety Research Unit<br><br>*◊ Search strategies ◊ Synthesising data ◊ Interpreting results ◊ Assessing risk of bias and publication bias*<br><br>**Learning objectives:**<br>• To obtain an overview of systematic reviews and meta-analyses |
| **1415 - 1420** | **Introduction to workshop on causation**<br>  <br>Dr Miranda Davies, Drug Safety Research Unit |
| **1420 - 1500** | **Workshop on causation**<br>Facilitators: Miranda Davies and Sandeep Dhanda<br><br>**Learning objectives:**<br>• 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. |
| **1500 - 1515** | **Coffee** |
| **1515 - 1525** | **Introduction to following workshop**<br>Mrs Lorna Hazell, Drug Safety Research Unit |
| **1525 - 1600** | **Workshop: Pharmacoepidemiology as a tool for risk management planning**<br>Facilitators: Lorna Hazell and Miranda Davies<br><br>**Learning objectives:**<br>• To define the key elements of a risk management plan using practical examples. |
| **1600 – 1615** | **Summing up and final questions** |
| **1615** | **Close of meeting** |

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