

DEVELOP  
YOUR SKILLS

IMPROVE YOUR  
CAREER

REALISE YOUR  
POTENTIAL

EXPAND YOUR  
KNOWLEDGE



Drug Safety Research Unit

## Introduction to Pharmacoepidemiology

Solent Hotel, Whiteley, Fareham

29 - 30 March 2023

Wednesday 29 March

**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**    **Registration**  
**(BST)**

---

**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 - 1045**    **Comfort break**

---

**1045 – 1115**    **Causality – Bradford Hill Criteria**

---

**1115 - 1120**    **Comfort break**

---

**1120 - 1205**    **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.

---

**1205 - 1210**    **Comfort break**

---

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

Prog draft 1 WEB (12P Mar 23)  
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at  
[www.dsru.org](http://www.dsru.org)




---

**1210 - 1255 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.

---

**1255 - 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 - 1520 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

---

**1520 - 1530 Comfort break**


---

**1530 – 1630 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.

---

**1630 - 1645 Question & Answer session**

Led by Dr Debabrata Roy, Drug Safety Research Unit

---

**1645 Close of day one**


---

**1650 - 1745 PMST trainees and Postgraduate Students ONLY are requested to meet the Assessor (Dr Debabrata Roy) to discuss their pre-course assignment for this course**

---

DEVELOP  
YOUR SKILLS

IMPROVE YOUR  
CAREER

REALISE YOUR  
POTENTIAL

EXPAND YOUR  
KNOWLEDGE



Drug Safety Research Unit

## Introduction to Pharmacoepidemiology

Solent Hotel, Whiteley, Fareham

29 - 30 March 2023

Wednesday 30 March

---

**0845 – 0900  
(BST)**

**Registration**

---

**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 - 1120**

**Comfort break**

---

**1120 - 1130**

**Introduction to interpretation of pharmacoepidemiological data workshop**

---

**1130 - 1215**

**Workshop on interpretation of pharmacoepidemiological data**

**Learning objectives:**

- To interpret published studies and critically evaluate the conclusions.

---

**1215 - 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:**

---

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

Prog draft 1 WEB (12P Mar 23)  
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at  
[www.dsru.org](http://www.dsru.org)

DEVELOP  
YOUR SKILLS

IMPROVE YOUR  
CAREER

REALISE YOUR  
POTENTIAL

EXPAND YOUR  
KNOWLEDGE



Drug Safety Research Unit

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

---

**1400 - 1405**    **Comfort break**

---

**1405 - 1410**    **Introduction to causation workshop**

---

**1410 - 1500**    **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.

---

**1500 - 1510**    **Coffee**

---

**1510 - 1520**    **Introduction to risk management planning workshop**

---

**1520 - 1600**    **Workshop: Pharmacoepidemiology as a tool for risk management planning**

**Learning objectives:**

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

---

**1600 - 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

---

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

Prog draft 1 WEB (12P Mar 23)  
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at  
[www.dsru.org](http://www.dsru.org)