



# DSRU

Drug Safety Research Unit

REALISE YOUR  
POTENTIAL

DEVELOP  
YOUR SKILLS

IMPROVE  
YOUR CAREER

EXPAND YOUR  
KNOWLEDGE

# Introduction to Pharmacoepidemiology

Hybrid Event: Solent Hotel, Whiteley & Online | 2 - 3 April 2025

Wednesday 2 April 2025

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**0830 - 0845 (BST)** Registration / Meeting room open for delegates to join

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**0845 - 0900** Introduction to the meeting

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**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*

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**0930 - 0935** Comfort break

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**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.

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**1035 - 1045** Coffee / Tea break

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**1045 - 1125** Causality – Bradford Hill Criteria

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**1125 - 1130** Comfort break

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**1130 - 1230** 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.

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**1230 - 1315** Lunch break

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Contact us on [EandT@dsru.org](mailto:EandT@dsru.org) or 023 8040 8600

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

Prog draft 1 WEB (12P Apr 25)

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

<b>1315 - 1400</b>	<b>Data resources for pharmacoepidemiology</b>  <i>◇ Broad overview of worldwide data resources ◇ Strengths and limitations of databases</i> <i>◇ Choosing an appropriate data resource ◇ ENCePP</i>  <b>Learning objectives:</b> To fully understand where you might search for data once a potential signal has been recognised.
<b>1400 - 1405</b>	<b>Comfort break</b>
<b>1405 - 1410</b>	<b>Introduction to methodology workshop</b>
<b>1410 - 1505</b>	<b>Workshop on methodology</b>  <b>Learning objectives:</b> <ul style="list-style-type: none"> <li>• 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.</li> </ul> To understand how study populations are selected.
<b>1505 - 1520</b>	<b>Coffee / Tea break</b>
<b>1520 - 1610</b>	<b>Interactive introduction to measures of disease frequency</b>  <i>◇ Key terms and concepts ◇ Descriptive statistics ◇ Calculating measures of frequency</i>  <b>Learning objectives:</b> To learn common techniques of analysis used to aid interpretation of pharmacoepidemiological investigations
<b>1610 - 1615</b>	<b>Comfort break</b>
<b>1615 - 1715</b>	<b>PASS, PAES and risk management</b>  <i>◇ Practical implications of ICHE2E ◇ Tailoring the approach ◇ Meeting the requirements of regulators ◇ Pitfalls to avoid ◇ ENCePP E-Register of Studies</i>  <b>Learning objectives:</b> <ul style="list-style-type: none"> <li>• To learn how pharmacoepidemiological methods are used in Post-authorisation Safety Studies (PASS) and Post-authorisation Efficacy Studies (PAES) in the UK and EU.</li> </ul> To understand how to incorporate pharmacoepidemiology into risk management planning.
<b>1715 - 1730</b>	<b>Question &amp; Answer session</b>
<b>1730</b>	<b>End of day one</b>
<b>1730 - 1815</b>	<b>PMST trainees and Postgraduate Students ONLY are requested to meet the Assessor to discuss their pre-course assignment for this course.</b>

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<b>0845 - 0900 (BST)</b>	<b>Registration / Meeting room open</b>
<b>0900 - 0905</b>	<b>Introduction to day 2 and recap of day 1</b>
<b>0905 - 1005</b>	<b>Interactive introduction to measures of impact and effect</b>  <i>◇ Key terms and concepts ◇ Calculating measures of impact and measures of effect (risk ratios, odds ratios and hazard ratios)</i>  <b>Learning objectives:</b> To learn common techniques of analysis used to aid interpretation of pharmacoepidemiological investigations
<b>1005 - 1015</b>	<b>Comfort break</b>
<b>1015 - 1100</b>	<b>Interactive introduction to data sampling issues</b>  <i>◇ Uncertainty and variation</i>  <b>Learning objectives:</b> To become familiar with underlying data sampling issues
<b>1100 - 1115</b>	<b>Question and answer session</b>
<b>1115 - 1130</b>	<b>Coffee / Tea break</b>
<b>1130 - 1140</b>	<b>Introduction to interpretation of pharmacoepidemiological data workshop</b>
<b>1140 - 1230</b>	<b>Workshop on interpretation of pharmacoepidemiological data</b>  <b>Learning objectives:</b> To interpret published studies and critically evaluate the conclusions.
<b>1230 - 1315</b>	<b>Lunch break</b>
<b>1315 - 1400</b>	<b>Introduction to systematic reviews and meta-analysis [DSS 3]</b>  <i>◇ Search strategies ◇ Synthesising data ◇ Interpreting results ◇ Assessing risk of bias and publication bias</i>  <b>Learning objectives:</b> To obtain an overview of systematic reviews and meta-analyses
<b>1400 - 1405</b>	<b>Comfort break</b>
<b>1405 - 1410</b>	<b>Introduction to causation workshop</b>
<b>1410 - 1500</b>	<b>Workshop on causation</b>  <b>Learning objectives:</b> 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.

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1500 - 1515	Coffee / Tea break
1515 - 1525	Introduction to risk management planning workshop
1525 - 1600	<p><b>Workshop: Pharmacoepidemiology as a tool for risk management planning</b></p> <p><b>Learning objectives:</b> To define the key elements of a risk management plan using practical examples.</p>
1600 - 1615	Summing up and final questions
1615	Close of meeting
1615 - 1630	<p><b>PMST trainees and Postgraduate Students</b></p> <p>Student Voice meeting to discuss any questions regarding the post-course assignment (<i>PMST trainees and Postgraduates</i>) or questions regarding the postgraduate programme in general (<i>Postgraduates only</i>)</p>