Spontaneous reporting methods have been traditionally used for signal detection purposes in pharmacovigilance. However, observational studies in pharmacoepidemiology are routinely conducted alongside existing spontaneous reporting methods in a complimentary manner. Pharmacoepidemiology is a key discipline for understanding the safety of medicines and vaccines and has made important contributions to our ongoing understanding of drug safety. It is also being increasingly recognised as a practical tool for supporting risk management and planning safety activities at the time medicines are authorised.

The ISoP pre-conference training day will provide an overview of the basic principles of pharmacoepidemiology as well as study design methods and approaches used in the pharmacoepidemiological analysis of observational datasets. Strengths and limitations of such methods and analytical approaches will be explained, and the main sources of data presented. The complimentary nature of spontaneous reporting and pharmacoepidemiological methods will also be discussed.

This course will be organised online on November 1st according to 4 sessions, including lectures, Q&As, and panel discussions.

Aims of the course

- To provide an overview in, and analysis of, core principles of pharmacoepidemiology
- To review study design methods and data sources used in pharmacoepidemiology
- To show how analytical techniques are applied to pharmacoepidemiological studies

Learning outcomes

- Discuss the complimentary nature of spontaneous reporting and pharmacoepidemiological methods
- Define and justify the elements of an ideal data source to be used to conduct a pharmacoepidemiological study
- Differentiate between common study design methods used in specific pharmacoepidemiological investigations
- Review common techniques of analysis in the interpretation of pharmacoepidemiological data for pharmacovigilance purposes
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0915 - 0930  Meeting room open for delegates to join
0930 - 0945  Welcome and introduction to the course  
Prof Saad Shakir, Drug Safety Research Unit
0945 - 1100  What is Pharmacoepidemiology in the context of Pharmacovigilance  
Prof Saad Shakir, Drug Safety Research Unit  
- Basic principles of pharmacoepidemiology  
- Strengths and limitations of spontaneous reporting  
- Bias and confounding in observational studies  
- The complimentary nature of spontaneous reporting and pharmacoepidemiological methods
1100 - 1130  Break
1130 - 1230  Data sources used in observational studies  
Dr Lorna Hazell, Drug Safety Research Unit  
- Strengths and limitations of various data sources
1230 - 1300  Interactive discussion  
Facilitators: Prof Saad Shakir and Dr Lorna Hazell  
*Topics selected by speakers and delegates will be discussed*
1300 - 1345  Break
1345 - 1500  Study design methods used in observational studies  
Dr Debabrata Roy, Drug Safety Research Unit  
- Strengths and limitations of various study design methods  
- Study design challenges to minimise bias
1500 - 1530  Break
1530 - 1645  Data analytics used in observational studies  
Dr Debabrata Roy, Drug Safety Research Unit  
- Overview of the methods and approaches used in pharmacoepidemiological analysis of observational datasets  
- Estimates, calculations, and interpretation of findings (interactive examples)  
- Analytical approaches to dealing with confounding  
- Strengths and limitations of various analytical approaches
1645 - 1700  Summing up and final questions  
Led by Dr Debabrata Roy, Drug Safety Research Unit
1700  Close of meeting