ISoP 2021 Annual Meeting - Pre-Conference Course I
01 November 2021

Pharmacoepidemiological methods in pharmacovigilance

(In collaboration with Drug Safety Research Unit -DSRU)

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

Training I	*GMT*	*CET*	*Oman*
November 01	*UTC*	*UTC+1*	*UTC+4*
Session A start	09:30	10:30	13:30
Session A end	11:00	12:00	15.00
Intermission 30'			
Session B start	11:30	12:30	15:30
Session B end	13:00	14.00	17.00
Intermission 45'			
Session C start	13:45	14.45	17:45
Session C end	15:00	16.00	19.00
Intermission 30'			
Session D start	15:30	16.30	19:30
Session D end	17:00	18.00	21.00

UTC/GMT		
Session A	**0930 - 0945**	**Welcome and introduction to the course** Prof Saad Shakir, Drug Safety Research Unit
Session A	**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
Session B	**1130 - 1230**	**Data sources used in observational studies** Lorna Hazell, Drug Safety Research Unit ○ Strengths and limitations of various data sources
	1230 - 1300	**Interactive discussion** Facilitators: Prof Saad Shakir and Lorna Hazell *Topics selected by speakers and delegates will be discussed*
	1300 - 1345	Break
Session C	**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
Session D	**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