Drug Safety Research Unit

Back to Basics in Pharmacovigilance

Solent Hotel, Whiteley near Fareham

26 – 27 February 2020

Wednesday 26 February

0815 - 0845	**Registration for delegates**
0845 - 0900	**Introduction to the meeting**
0900 – 1015	**Definitions, History, Classifications of ADRs, Basic Principles of Pharmacovigilance [DSS 1, 3]** ◊ *Definition of pharmacovigilance* ◊ *History of pharmacovigilance* ◊ *Operational definitions (serious, non-serious, expected, unexpected)* ◊ *Classification of ADRs* ◊ *Basic causality assessment* ◊ *Characteristics of different systems of reporting* ◊ *Strengths* ◊ *Weaknesses* ◊ *Definitions Medication errors, off-label, overdose, misuse* **Learning objectives**: • To revise founding principles of pharmacovigilance • To become familiar with current ICH and regulatory basic definitions and be aware of change during interpretation both in the EU and USA • To understand simple causality assessment, the principles behind current spontaneous reporting systems, and the logic behind pharmacovigilance planning (ICHE2E)
1015 - 1030	**Coffee**
1030 - 1115	**Ethics and transparency in pharmacovigilance [DSS 1]** **Learning objectives:** • For you to consider relevant ethical principles from an individual and societal point of view and outline the available ethical safeguards • To provide you with an understanding of main issues relating to transparency in pharmacovigilance i.e. availability of data and information about processes, and conflicts of interest
1115 - 1125	**Introduction to interactive session: History of Pharmacovigilance**
1125 - 1255	**Interactive session: History of Pharmacovigilance** ◊ *Case study: SSRIs / Coxibs*
1255 - 1345	**Lunch**

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1345 - 1445	**Interactive introduction to international collaboration in pharmacovigilance [DSS 1,2, 3, 4, 8]** *◊ Review of the structure of ICH and how guidelines are developed (ICHE2BM, ICH E2C (PSURs/PBRERs), ICHE6 (GCP), ICHE3 (reporting standards)) ◊ CIOMS – outlines of: I, II and V (spontaneous reporting, CCSI, DCSI); IV (risk benefit assessment) and VI (clinical trials) ◊ Aggregate reports PSURs/PBRERs/DSURs ◊ PILs* **Learning objectives:** • Gain an understanding of the need for global pharmacovigilance and in particular for standardisation of collection and monitoring of data and the principles of risk benefit analysis
1445 - 1500	**Tea**
1500 - 1545	**Interactive introduction to international collaboration in pharmacovigilance [DSS 1,2, 3, 4, 8]**
1545 – 1645	**Digital and social media for pharmacovigilance** **Learning objectives:** • To review regulations and guidelines for pharmacovigilance associated with digital media • To develop an understanding of the landscape of social media including the key concepts of pharmacovigilance and social media, focusing on company-sponsored activities, and including patient-centred sites • To assess the content of social media as a source of individual case safety reports • To understand the potential for signal detection using aggregated data from digital media sources • To receive an introduction to the Web-RAdR IMI project including an assessment of the capabilities of social media for pharmacovigilance and benefit risk reporting by patients • To consider how digital media will impact the current operating model for pharmacovigilance
1645	**Close of day one**
1645 - 1745	**PMST trainees and Postgraduate Students ONLY are requested to meet the Assessors (Dr Vicki Osborne & Jean Kilgour-Christie) to discuss their pre-course assignment for this course**
1745 – 1815	**Complimentary networking drinks reception**

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0830 - 0845	**Registration**
0830 - 0845	**PMST trainees and Postgraduate in Pharmacovigilance students only** Student meeting
0845	**Start of day 2**
0845 - 1015	**Regulatory aspects of pharmacovigilance – post-marketing [DSS 1, 2, 3, 4]** *◊ Legal basis of pharmacovigilance ◊ Roles of MHRA, CHM, EMA, CHMP, PRAC ◊ Relevant Guidelines* **Learning objectives:** • To understand the legal principles of pharmacovigilance and the enactment of European legislation directly for pharmaceuticals
1015 - 1115	**Regulatory aspects of pharmacovigilance – premarketing [DSS 1, 2, 3, 4]** *◊ New clinical trial regulation ◊ Clinical trials Directive ◊ FDA (roles and responsibilities of therapeutic diagnoses, epidemiology group, Medwatch and AERS) ◊ FDA guidelines, points to consider and PDUFA III* **Learning objectives:** • To provide you with an understanding of the legal principles of pharmacovigilance through the enactment of EU and US legislation directly for pharmaceuticals
1115 - 1130	**Coffee**
1130 - 1245	**Current practical pre-marketing Drug Safety [DSS 1, 2, 4]** *◊ ADR reporting rules ◊ Clinical trials directive requirements ◊ US PDUFA III aspects of safety monitoring ◊ High mortality clinical trials ◊ DSMBs ◊ DCSIs and the concept of expectedness* **Learning objectives:** • To familiarise yourself with the differences of pharmacovigilance reporting in clinical trials and especially pre-registration
1245 - 1330	**Lunch**
1330 - 1415	**Pre-marketing safety monitoring and evaluation [DSS 1, 2, 3, 4]** *◊ Principles of risk benefit safety assessment within a clinical development plan ◊ Preclinical*

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	safety assessment ◊ Phase I ◊ Phase II ◊ Phase III **Learning objectives:** • To achieve an understanding of the approach to developing the safety data base on which the risk benefit evaluation of a new medicinal product will be based
1415 - 1425	**Introduction to interactive session: Reporting adverse drug reactions**
1425 - 1525	**Interactive session: Reporting adverse drug reactions**
1525 - 1545	**Tea**
1545 - 1645	**Practical aspects of signal detection [DSS 1, 3]** *◊ Handling of signals in Pharmaceutical Companies ◊ Pre-licensing vs post-licensing issues ◊ Systems and software for detecting signals ◊ Regulatory interactions ◊ Interface between signals and risk-management strategies ◊Coding systems for drug safety* **Learning objectives:** • To understand how pharmaceutical companies approach signal detection and management, and the resources available to them
1645 - 1730	**Impact of adverse drug reactions [DSS 8]** *◊ Informed consent ◊ PILs, provision of information ◊ When things go wrong ◊ Consumer groups* **Learning objectives:** • To understand how patients, carers and the public understand risk benefit and perceive pharmacovigilance. To illustrate pharmaceutical obligations. Followed by; **New developments in pharmacovigilance [DSS 1, 3, 4, 8]** *◊ ICHE2E and Risk management planning ◊ Future directions ◊ Safety aspects of advanced therapies* **Learning objectives:** • To discuss new methods for detection and prioritisation of signals derived from spontaneous ADR reports
1730	**Close of meeting**

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