Drug Safety Research Unit

Back to Basics in Pharmacovigilance

Solent Hotel, Whiteley, Fareham and online

6 - 7 September 2023

Wednesday 6 September

0830 - 0845 (BST)	**Registration**
0845 - 0900	**Introduction to the meeting**
0900 - 1030	**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)
1030 - 1045	**Coffee break**
1045 - 1125	**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
1125 - 1135	**Comfort break**
1135 - 1145	**Introduction to interactive session: History of Pharmacovigilance**
1145 - 1300	**Interactive session: History of Pharmacovigilance** *◊ Case study: SSRIs / Coxibs*
1300 - 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 - 1455	**Comfort break**
1455 - 1540	**Interactive introduction to international collaboration in pharmacovigilance [DSS 1,2, 3, 4, 8] continued**
1540 - 1555	**Coffee break**
1555 - 1655	**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
1655	**Close of day one**
1700 - 1745	**Postgraduate Students ONLY are requested to meet the Assessors to discuss their pre-course assignment for this course**

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Thursday 7 September

0830 - 0845 (BST)	**Registration**
0845	**Start of day 2**
0845 - 0930	**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
0930 - 0935	**Comfort break**
0935 - 1020	**Regulatory aspects of pharmacovigilance – post-marketing continued [DSS 1, 2, 3, 4]**
1020 - 1035	**Coffee break**
1035 - 1135	**Regulatory aspects of pharmacovigilance – premarketing [DSS 1, 2, 3, 4]** **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
1135 - 1145	**Comfort break**
1145 - 1250	**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
1250 - 1335	**Lunch**
1335 - 1425	**Pre-marketing safety monitoring and evaluation [DSS 1, 2, 3, 4]** *◊ Principles of risk benefit safety assessment within a clinical development plan ◊ Preclinical safety assessment ◊ Phase I ◊ Phase II ◊ Phase III* **Learning objectives:**

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	• 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
1425 - 1435	**Comfort break**
1435 - 1535	**Interactive session: Reporting adverse drug reactions**
1535 - 1550	**Coffee break**
1550 – 1635	**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
1635 - 1645	**Comfort break**
1645 - 1745	**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
1745	**Close of meeting**
1745 - 1800	**Postgraduate in Pharmacovigilance students only** Student meeting to discuss any questions regarding the post-course assignment