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Drug Safety Research Unit

# Back to Basics in Pharmacovigilance

Solent Hotel, Whiteley near Fareham

**2 - 3 September 2020**

**Wednesday 2 September**

| | |
|---|---|
| **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]**<br><br>*◊ 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*<br><br>**Learning objectives**:<br>• To revise founding principles of pharmacovigilance<br>• To become familiar with current ICH and regulatory basic definitions and be aware of change during interpretation both in the EU and USA<br>• 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]**<br><br>**Learning objectives:**<br>• For you to consider relevant ethical principles from an individual and societal point of view and outline the available ethical safeguards<br>• 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**<br>*◊ 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]**<br><br>*◊ 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*<br><br>**Learning objectives:**<br>• 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**<br><br>**Learning objectives:**<br>• To review regulations and guidelines for pharmacovigilance associated with digital media<br>• 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<br>• To assess the content of social media as a source of individual case safety reports<br>• To understand the potential for signal detection using aggregated data from digital media sources<br>• 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<br>• 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 to discuss their pre-course assignment for this course** |
| **1745 – 1815** | **Complimentary networking drinks reception** |

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**2 – 3 September 2020**

**Thursday 3 September**

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| **0830 - 0845** | **Registration** |
| **0830 - 0845** | **PMST trainees and Postgraduate in Pharmacovigilance students only**<br>Student meeting |
| **0845** | **Start of day 2** |
| **0845 - 0930** | **Regulatory aspects of pharmacovigilance – post-marketing [DSS 1, 2, 3, 4]**<br><br>*◊ Legal basis of pharmacovigilance ◊ Roles of MHRA, CHM, EMA, CHMP, PRAC ◊ Relevant Guidelines*<br><br>**Learning objectives:**<br>• To understand the legal principles of pharmacovigilance and the enactment of European legislation directly for pharmaceuticals |
| **0930 – 0940** | **Break** |
| **0940 - 1025** | **Regulatory aspects of pharmacovigilance – post-marketing continued [DSS 1, 2, 3, 4]** |
| **1025 - 1125** | **Regulatory aspects of pharmacovigilance – premarketing [DSS 1, 2, 3, 4]**<br><br>*◊ 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*<br><br>**Learning objectives:**<br>• To provide you with an understanding of the legal principles of pharmacovigilance through the enactment of EU and US legislation directly for pharmaceuticals |
| **1125 - 1140** | **Coffee** |
| **1140 - 1255** | **Current practical pre-marketing Drug Safety [DSS 1, 2, 4]**<br><br>*◊ 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*<br><br>**Learning objectives:** |

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- To familiarise yourself with the differences of pharmacovigilance reporting in clinical trials and especially pre-registration

**1255 - 1345** **Lunch**

**1345 - 1430** **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:**

- 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

**1430 - 1440** **Introduction to interactive session: Reporting adverse drug reactions**

**1440 - 1540** **Interactive session: Reporting adverse drug reactions**

**1540 - 1555** **Tea**

**1555 – 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

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| | spontaneous ADR reports |
| **1730** | **Close of meeting** |

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