DEVELOP YOUR SKILLS

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Drug Safety Research Unit

Risk Benefit Assessment in Pharmacovigilance

Solent Hotel, Whiteley near Fareham

9 - 10 October 2019

Chairperson: Dr Miranda Davies

Wednesday 9 October

0830 - 0900	**Registration for delegates**
0900 - 0915	**Welcome and introduction to the course**
0915 - 1000	**Risk benefit evaluation – an overview [DSS 3, 4]** **Learning objectives**: • To understand benefit-risk assessment, risk management cycle and also CIOMS IV proposals. • To link all aspects of benefit-risk evaluation and illustrate the co-ordination that is required at all levels, i.e. data, data collection, evaluation and decision making.
1000 - 1045	**Definition and measurement of risk** *◊ Definitions ◊ Risk analysis ◊ Basic pharmacoepidemiology ◊ Population at risk ◊ Measures of association ◊ Concept of Relative Risk, Number needed to harm, Odds ratio and other parameters* **Learning objectives**: • To learn how risk may be evaluated statistically and otherwise.
1045 - 1100	**Coffee**
1100 - 1130	**Identification and evaluation of risk [DSS 3, 5]** *◊ Risk identification ◊ Internal/external data sources ◊ Evaluation of a signal ◊ Prioritisation of risk ◊ Causality assessment ◊ Risk minimisation ◊ Evidence-based medicine ◊* **Learning objectives:** • To know where to look for signals and how to prioritise what you find and also how to trawl for further information in case series.
1130 - 1230	**Formal and informal benefit-risk decision tools [DSS 4]** **Learning objectives:** • To understand the value and applicability of formal and informal benefit-risk decision tools pre- and post-approval, to learn about their main features, and to understand the most valuable tools in more detail. This should enable you to apply these tools yourself and understand their advantages and limitations.
1230 - 1330	**Lunch**

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1330 - 1335	**Introduction to workshop: making risk-benefit judgements**
1335 - 1430	**Workshop: making risk-benefit judgements [DSS 3 & 4]** *◊ Judge the overall balance of risks and benefits ◊ Consider in what circumstances the risk-benefit could be judged positive ◊ Propose studies and measures aimed at maximising the balance of benefit and risk* **Learning objectives:** • To be able to illustrate the challenges of making risk-benefit judgements at the population level using high level information for three topical and important issues
1430 - 1530	**Overview of regulations and guidelines governing risk benefit (ICH, EMA, CPMP, FDA) [DSS 1, 2, 3 & 4]** *◊ CIOMS IV ◊ IB (DCSI) Annual updates (IB, Clinical Trials Directive, IND) ◊ Common Technical Document ◊ ICH clinical safety guidelines (including PSURs) ◊ CPMP/FDA guidelines ◊ FDA including PDUFA III* **Learning objectives:** • To understand the plethora of regulations and guidelines that govern identifying, analysing, prioritising and monitoring risk.
1530 - 1545	**Tea**
1545 - 1630	**Practical implications of completing regulatory requirements [DSS 1, 2 & 3]** *◊ SOPs and compliance ◊ Annual updates for clinical trial programmes ◊ Templates for documents ◊ Timetabling and planning ◊ Cross functional teams ◊ QA and compliance ◊ Routine ADR reporting and unexpected events – how often and when do I need to do something* **Learning objectives:** • To appreciate the practical aspects of implementing regulations and guidelines. • To gain an awareness of resource and time implications for planning safety reporting including providing tips for planning and for making such activities more efficient.
1630 - 1700	**Risk management – taking action [DSS 1, 2, 3, 5, 6 & 7]** *◊ Minimising risks with medicines ◊ Regulatory actions ◊ Risk Management Plans ◊ Choosing the right risk minimisation activities ◊ Issue management* **Learning objectives:** • To understand the different activities which may be undertaken to manage and minimise known risks (i.e. risk resolution)
1700	**Close of day one**
1700 - 1800	**ONLY PMST and Postgraduate Candidates' Risk Benefit Presentations/Discussions [DSS 3 & 4]**
1800	**Complimentary networking drinks reception**

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0845 - 0900	**Registration**
0845 - 0900	**Postgraduate in Pharmacovigilance students only** Student meeting
0900	**Start of day 2**
0900 - 1000	**Using Multi-Criteria Decision Analysis (MCDA) for benefit-risk evaluation: methods options and good practice**
1000 - 1100	**Routine risk minimisation via safety information documents [DSS 1, 2, 5 & 6]** ◊ *SmPC* ◊ *PIL* ◊ *CCSI* ◊ *External communications* **Learning objectives:** • To know the safety sections in the SmPC and the PIL, highlighting the opportunities for managing risk and how to avoid ambiguities which could arise from the inevitable replication (especially in the SmPC). • To understand the CCSI and how this may differ in content and use from regional and local data sheet and prescribing safety information.
1100 - 1115	**Coffee**
1115 - 1120	**Introduction to workshop: crisis management**
1120 - 1215	**Workshop: crisis management [DSS 5, 6 & 7]** **Learning objectives:** • To appreciate the challenges faced in a major drug safety crisis and understand the principles for (1) deciding what actions should be taken (2) successfully managing a crisis.
1215 - 1300	**Risk benefit – a regulators perspective** **Benefit-risk assessment throughout the drug lifecycle**

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1300 - 1345	**Lunch**
1345 - 1430	**Benefit-risk assessment in Periodic Safety Reports – PBRERs and DSURs [DSS 1, 2, 6 & 8]** *◊ Evolution of PSURs from PBRERs ◊ How to approach benefit-risk in the context of the PBRER ◊ The role of the DSUR, and the challenges of ongoing benefit-risk evaluation in clinical development* **Learning objectives:** • To understand the importance of the PBRER/PSUR, and the role of the DSUR, in the benefit-risk management process
1430 - 1445	**Discussion**
1445 - 1500	**Tea**
1500 - 1505	**Introduction to workshop: communication of safety issues**
1505 - 1600	**Workshop: communication of safety issues [DSS 2, 6 & 7]** **Learning objectives:** • To understand the principles and practical issues involved in communicating successfully about a major drug safety concern. You will be given information based on a real-life issue and asked to (1) develop a communication plan (2) produce a draft letter to health professionals.
1600	**Close of meeting**

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