DEVELOP YOUR SKILLS

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EXPAND YOUR KNOWLEDGE

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** Dr Miranda Davies, Drug Safety Research Unit
0915 - 1000	**Risk benefit evaluation – an overview [DSS 3, 4]**  Dr Miranda Davies, Drug Safety Research Unit **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**  Lorna Hazell, Drug Safety Research Unit *◊ 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]** Lorna Hazell, Drug Safety Research Unit *◊ 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]**  Dr Lesley Wise, Wise PV and Risk Management Ltd **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.

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1230 - 1330	**Lunch**
1330 - 1415	**Risk benefit – a regulators perspective** **Benefit-risk assessment throughout the drug lifecycle** Alison Shaw, Medicines & Healthcare products Regulatory Agency (MHRA)
1415 - 1420	**Introduction to workshop: making risk-benefit judgements** Dr Miranda Davies, Drug Safety Research Unit
1420 - 1515	**Workshop: making risk-benefit judgements [DSS 3 & 4]** Facilitators: Glyn Belcher and Miranda Davies *◊ 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
1515 - 1530	**Tea**
1530 - 1615	**A worked example of Benefit-Risk Action Team (BRAT) methodology** Dr Miranda Davies & Dr Debabrata Roy, Drug Safety Research Unit
1615 - 1645	**Risk management – taking action [DSS 1, 2, 3, 5, 6 & 7]** Dr Glyn Belcher, PV Consultancy Ltd *◊ 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)
1645	**Close of day one**
1645 - 1745	**ONLY PMST and Postgraduate Candidates'** **Risk Benefit Presentations/Discussions [DSS 3 & 4]** Facilitators: Glyn Belcher and Miranda Davies
1745	**Complimentary networking drinks reception**

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0845 - 0900	**Registration**
0845 - 0900	**Postgraduate in Pharmacovigilance students and PMSTs only** Student meeting
0900	**Start of day 2**
0900 - 0945	**Practical implications of completing regulatory requirements [DSS 1, 2 & 3]**  Dr Anne-Ruth van Troostenburg de Bruyn, Gilead Sciences International Ltd *◊ 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.
0945 - 1030	**Urgent re-evaluation of benefit-risk of a marketed product** Article 20 Dr Anne-Ruth van Troostenburg de Bruyn, Gilead Sciences International Ltd
1030 - 1045	**Coffee**
1045 - 1145	**Routine risk minimisation via safety information documents [DSS 1, 2, 5 & 6]**  Dr Kristina Strutt, Sanofi *◊ 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.

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1145 - 1150	**Introduction to workshop: crisis management** Dr Miranda Davies, Drug Safety Research Unit
1150 - 1245	**Workshop: crisis management [DSS 5, 6 & 7]** Facilitators: Dr Miranda Davies, Dr Kristina Strutt and Dr Vicki Osborne **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.
1245 - 1330	**Lunch**
1330 - 1415	**Benefit-risk assessment in Periodic Safety Reports – PBRERs and DSURs [DSS 1, 2, 6 & 8]** Dr Kristina Strutt, Sanofi *◊ 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
1415 - 1430	**Discussion**
1430 - 1445	**Tea**
1445 - 1450	**Introduction to workshop: communication of safety issues** Dr Miranda Davies, Drug Safety Research Unit
1450 - 1545	**Workshop: communication of safety issues [DSS 2, 6 & 7]** Facilitators: Dr Miranda Davies, Dr Kristina Strutt and Dr Vicki Osborne **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.
1545	**Close of meeting**

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