DSRU
Drug Safety Research Unit

REALISE YOUR POTENTIAL
DEVELOP YOUR SKILLS
IMPROVE YOUR CAREER
EXPAND YOUR KNOWLEDGE

Risk Benefit Assessment in Pharmacovigilance

Hybrid Event: Solent Hotel, Whiteley and Online | 25 – 26 September 2024

Wednesday 25 September 2024

0845 - 0900 (BST)	**Registration / Meeting room open for delegates to join**
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 - 1005	**Comfort break**
1005 - 1050	**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.
1050 - 1105	**Coffee / Tea break**
1105 - 1135	**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.
1135 - 1140	**Comfort break**

1140 - 1240	**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.
1240 - 1330	**Lunch break**
1330 - 1415	**Risk benefit – a regulators perspective** **Benefit-risk assessment throughout the drug lifecycle**
1415 - 1420	**Comfort break**
1420 - 1425	**Introduction to workshop: making risk-benefit judgements**
1425 - 1520	**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
1520 - 1535	**Coffee / Tea break**
1535 - 1620	**A worked example of Benefit-Risk Action Team (BRAT) methodology**
1620 - 1625	**Comfort break**
1625 - 1655	**Taking action – MAH point of view [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)
1655	**End of day one**
1655 - 1745	**PMST trainees and Postgraduate students only** Meet with the course leader for pre-course assignment presentations / discussion

Thursday 26 September 2024

0845 - 0900 (BST)	**Registration / Meeting room open**
0900	**Start of day 2**
0900 - 0945	**Urgent re-evaluation of benefit-risk of a marketed product. Article 20** *◊ 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.
0945 - 0950	**Comfort break**
0950 - 1035	**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.
1035 - 1050	**Coffee / Tea break**
1050 - 1200	**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.
1200 - 1300	**Lunch break**
1300 - 1305	**Introduction to workshop: crisis management**
1305 - 1405	**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.
1405 - 1420	**Coffee / Tea break**
1420 - 1425	**Introduction to workshop: communication of safety issues**

1425 - 1525	**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.
1525 - 1535	**Comfort break**
1535 - 1620	**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
1620 - 1640	**Discussion session**
1640	**Close of meeting**
1640 - 1700	**PMST trainees and Postgraduate in Pharmacovigilance students only** Student Voice meeting to discuss any questions regarding the post-course assignment *(PMST trainees and Postgraduates)* or post-graduate programme *(Postgraduates only)*