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Drug Safety Research Unit

Risk Benefit Assessment in Pharmacovigilance

4 - 5 October 2023

Wednesday 4 October

0845 - 0900 (BST)	Registration
0900 - 0915	Welcome and introduction to the course
0915 - 1000	Risk benefit evaluation – an overview [DSS 3, 4] Learning objectives: <ul style="list-style-type: none">• 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 <i>◇ Definitions ◇ Risk analysis ◇ Basic pharmacoepidemiology ◇ Population at risk ◇ Measures of association ◇ Concept of Relative Risk, Number needed to harm, Odds ratio and other parameters</i> Learning objectives: <ul style="list-style-type: none">• To learn how risk may be evaluated statistically and otherwise.
1050 - 1100	Coffee
1100 - 1130	Identification and evaluation of risk [DSS 3, 5] <i>◇ Risk identification ◇ Internal/external data sources ◇ Evaluation of a signal ◇ Prioritisation of risk ◇ Causality assessment ◇ Risk minimisation ◇ Evidence-based medicine ◇</i> Learning objectives: <ul style="list-style-type: none">• 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 - 1135	Comfort break
1135 - 1235	Formal and informal benefit-risk decision tools [DSS 4] Learning objectives: <ul style="list-style-type: none">• 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.
1235 - 1330	Lunch break

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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] <i>◇ 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</i> Learning objectives: <ul style="list-style-type: none">• 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 - 1530	Comfort break
1530 - 1615	A worked example of Benefit-Risk Action Team (BRAT) methodology
1615 - 1620	Comfort break
1620 - 1650	Taking action – MAH point of view [DSS 1, 2, 3, 5, 6 & 7] <i>◇ Minimising risks with medicines ◇ Regulatory actions ◇ Risk Management Plans ◇ Choosing the right risk minimisation activities ◇ Issue management</i> Learning objectives: <ul style="list-style-type: none">• To understand the different activities which may be undertaken to manage and minimise known risks (i.e., risk resolution)
1650	Close of day one
1655 - 1745	ONLY PMST and Postgraduate Candidates’ Risk Benefit Presentations/Discussions [DSS 3 & 4]

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Thursday 5 October

0845 - 0900 (BST)	Registration
0900	Start of day 2
0900 - 1000	Practical implications of completing regulatory requirements [DSS 1, 2 & 3] <i>◇ 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</i> Learning objectives: <ul style="list-style-type: none">• 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.
1000 - 1010	Comfort break
1010 - 1115	Routine risk minimisation via safety information documents [DSS 1, 2, 5 & 6] <i>◇ SmPC ◇ PIL ◇ CCSI ◇ External communications</i> Learning objectives: <ul style="list-style-type: none">• 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.
1115 - 1125	Comfort break
1125 - 1130	Introduction to workshop: crisis management
1130 - 1230	Workshop: crisis management [DSS 5, 6 & 7] Learning objectives: <ul style="list-style-type: none">• 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.
1230 - 1315	Lunch break
1315 - 1320	Introduction to workshop: communication of safety issues

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1320 - 1420 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.

1420 - 1430 Comfort break

1430 - 1515 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

1515 - 1545 Discussion

1545 Close of meeting

1545 - 1600 Postgraduate in Pharmacovigilance students and PMSTs only
Student meeting to discuss any questions regarding the post-course assignment

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