DEVELOP YOUR SKILLS

IMPROVE YOUR CAREER

REALISE YOUR POTENTIAL

EXPAND YOUR KNOWLEDGE

Drug Safety Research Unit

Pharmacovigilance Planning and Risk Management

Hybrid event: Solent Hotel, Whiteley and Online

28 – 29 September 2022

Chairperson: Dr Alison Evans

Wednesday 28 September

0830 – 0900 (BST)	**Registration**
0900 - 0905 	**Welcome and introduction to the course** Dr Alison Evans, Drug Safety Research Unit
0905 - 0950 	**Risk management in pharmacovigilance – the background** Dr Miranda Davies, Drug Safety Research Unit **Learning objectives**: • To understand the origins and purposes of risk management plans; to discuss how they are used in practice and how risk management is continuing to develop
0950 - 0955	**Comfort break**
0955 - 1050 	**Risk Management Planning: an industry perspective** Muhammad Haris Shaikh, Ipsen **Learning objectives:** • To appreciate, from a company point of view, the production and approval of a risk management plan and factors to be considered in implementation of the plan. • To discuss updating of risk management plans and reporting of effectiveness of enhanced risk minimisation activities.
1050 - 1105	**Coffee break**
1105 - 1200	**Risk Management: a regulatory perspective** **Learning objectives:** To outline the different sections of the risk management plan; to discuss the information to be included for each section; to discuss current experience of assessing risk management plans from a regulator's perspective
1200 - 1205	**Comfort break**
1205 - 1300	**Open forum discussion: With a case study about the interaction between industry, regulators and Risk Management**

Book your place here: https://www.dsru.org/education-training/
Contact us on EandT@dsru.org or 023 8040 8600

1300 - 1345	**Lunch**
1345 - 1445	**The life span of a risk management plan** Bridget King, BJK Pharma Consulting Ltd **Learning objectives:** • To understand the life span of the RMP from the development RMP to the mature RMP • To consider the role of the core RMP
1445 - 1500	**Coffee break**
1500 - 1600	**Development risk management plans: A case study in planning for the future** Bridget King, BJK Pharma Consulting Ltd **Learning objectives:** • To understand the strategic approach to risk management planning during drug development
1600	**Close of day one**
1600 - 1630	**Postgraduate candidates' presentations / discussion**

Book your place here: https://www.dsru.org/education-training/
Contact us on EandT@dsru.org or 023 8040 8600

DEVELOP YOUR SKILLS

IMPROVE YOUR CAREER

REALISE YOUR POTENTIAL

EXPAND YOUR KNOWLEDGE

Drug Safety Research Unit

Pharmacovigilance Planning and Risk Management

Hybrid event: Solent Hotel, Whiteley and Online

28 – 29 September 2022

Chairperson: Dr Alison Evans

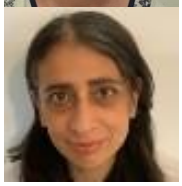
Thursday 29 September

0845 – 0900 (BST)	**Registration**
0900 - 0905 	**Introduction to day 2** Dr Alison Evans, Drug Safety Research Unit
0905 - 1015	**Studies for risk management - researcher's experience and handling challenges** Dr Alison Evans, Drug Safety Research Unit
1015 - 1030	**Coffee break**
1030 - 1150	**Risk management plans: the design of post-marketing studies (Presentation & interactive session)** **Learning objectives:** To understand the factors important in the design of PE studies used as tools to support RMPs and to introduce you to operational research standards that should be considered when conducting PE and PhV research
1150 - 1155	**Comfort break**
1155 - 1255 	**An overview of risk minimisation and studying its effectiveness** Dr Debabrata Roy, Drug Safety Research Unit **Learning objectives**: • To be aware of the principal methods available to manage risks associated with medicines and to provide a framework for discussing how these can be better utilised and/or improved.
1255 - 1340	**Lunch**
1340 - 1455 	**Interactive session on defining and designing risk minimisation measures** Facilitators: Dr Joanne Treacy and Dr Alison Evans

Book your place here: https://www.dsru.org/education-training/
Contact us on EandT@dsru.org or 023 8040 8600

Prog draft 6 WEB (RMP 22)
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at
www.dsru.org

1455 - 1510	**Coffee break**
1510 - 1610	**Special cases in risk management**   Valerie Joynson and Fahimeda Ali, Medicines & Healthcare products Regulatory Agency (MHRA) **Learning objectives:** • To learn about issues specific to the risk management of vaccines and medicines in children. • To describe particular requirements for the risk management plan and further points to consider in the planning of pharmacovigilance measures.
1610 - 1630	**Question and Answer session** Dr Alison Evans, Drug Safety Research Unit
1630	**Close of meeting**

Book your place here: https://www.dsru.org/education-training/
Contact us on EandT@dsru.org or 023 8040 8600