Drug Safety Research Unit

Periodic Safety Reports – PSURs/PBRERs and Introduction to DSURs

Solent Hotel, Whiteley near Fareham

6 – 7 May 2020

Wednesday 6 May

0845 - 0915	**Registration for delegates**
0915 - 0930	**Welcome and introduction to the course**
0930 - 1045	**Periodic Safety Reports – what are they for?** **Learning objective (1):** • To understand the history of PSURs and rationale for writing PSURs. ◊ Evolution of PSURs from CIOMS II to ICH, to EU PV legislation ◊ ICH E2C R1 and R2 ◊ CIOMS V ◊ Importance during early post-marketing years **Learning objective (2):** • To understand the regulatory aspects of PBRERs ◊ Guidance and regulations ◊ Reporting requirements ◊ Renewals ◊ Assessment process ◊ PBRER outcomes ◊ Compliance
1045 - 1100	**Coffee**
	PSURs/PBRERs
1100 - 1145	**Core Safety Information and local datasheets** ◊ Development core safety information ◊ Company core safety information ◊ Listed (PBRER) vs labelled (expedited reporting) ◊ Safety sections in the SPC **Learning objectives:** • To learn the concepts of the company core datasheet, the company core safety information and local datasheets
1145 - 1230	**Patient exposure for PBRERs** ◊ Exposure data from clinical trials ◊ Post-marketing exposure data ◊ Practicalities in obtaining exposure data **Learning objectives:** • To discuss sources of exposure data for a PBRER
1230 - 1300	**Discussion and questions**
1300 - 1345	**Lunch**

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

1345 - 1430	**PBRERs: Signal and risk evaluation** ◊ Links to the Risk Management Plan **Learning objectives:** • To discuss the guidance given for the Signal and risk Evaluation section of the PBRER
1430 - 1435	**Introduction to workshop: Signal and risk evaluation**
1435 - 1600	**Workshop: Signal and risk evaluation (group work)** **Learning objectives:** • To give you practical experience in reviewing data to evaluate signals and risks and writing this section of the PBRER
1600 - 1615	**Tea**
1615 - 1645	**Planning, writing and reviewing a PBRER** ◊ The PBRER process ◊ Factors to consider in estimating time and resources needed to complete PBRER ◊ Use of contributors from other parts of company ◊ The writing process ◊ Reaching a conclusion ◊ Reviewing PBRERs **Learning objectives:** • To discuss the planning, writing and reviewing of a PBRER
1645	**Close of day one**
1645 - 1715	**Complimentary networking drinks reception**

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

Drug Safety Research Unit

Periodic Safety Reports – PSURs/PBRERs and Introduction to DSURs

Solent Hotel, Whiteley near Fareham

6 – 7 May 2020

Thursday 7 May

0830 – 0845	**Registration**
0830 - 0845	**Postgraduate in Pharmacovigilance students only** Student meeting
0845 - 0930	**Benefit evaluation** **Integrated benefit-risk analysis** ◊ Benefit information to include ◊ Characterisation of benefits ◊ Benefit-risk context and evaluation **Learning objectives:** • To understand the scope of benefit-risk evaluation required in the new EU PBRERs, and outline the principles involved to achieve this
0930 - 1030	**PBRERs: Clinical studies** ◊ How to find information on studies ◊ Who to consult over study methodology and findings ◊ What to report from studies and published literature? **Learning objectives:** • To learn the types of studies and published literature which may be suitable for inclusion in a PBRER
1030 - 1045	**Coffee**
1045 - 1130	**Published literature** ◊ Search strategies ◊ Obtaining search results ◊ Presentation of literature in PBRERs **Learning objectives:** • To understand how to handle published literature in PBRERs.
1130 - 1230	**Reviewing and evaluating a PBRER: the regulator's perspective** ◊ Key criteria for a high quality PBRER **Learning objectives:** • To obtain an appreciation of the regulatory authority's expectations
1230 - 1315	**Lunch**

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

1315 - 1320	**Introduction to workshop: Reviewing a PBRER**
1320 - 1415	**Workshop: Reviewing a PBRER (group work)** **Learning objective:** To give you practical experience in reviewing sections of a PSUR
1415 - 1500	**Regulatory Assessment of PSURs**
1500 - 1515	**Tea**
	DSURs
1515 - 1615	**DSURs** **Learning objectives:** • To understand the content of DSURs, including: Reference Safety Information; presentation of efficacy and safety data; regulatory assessment; synergies with the PSUR/PBRER
1615 - 1645	**Final discussion and questions**
1645	**Close of meeting**

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