



DSRU

Drug Safety Research Unit

REALISE YOUR
POTENTIAL

DEVELOP
YOUR SKILLS

IMPROVE
YOUR CAREER

EXPAND YOUR
KNOWLEDGE

Periodic Safety Reports – PSURs/PBRERs and relationship to DSURs

Hybrid Event: Solent Hotel, Whiteley & Online | 1 - 2 May 2024

Chairperson and Course Leader: Dr Kristina Strutt

Wednesday 1 May 2024

0900 - 0915 (BST) Registration / Meeting room open for delegates to join

0915 - 0930 **Welcome and introduction to the course**
Dr Kristina Strutt, MorphoSys AG

0930 - 1045 **Periodic Safety Reports – what are they for?**
Dr Kristina Strutt, MorphoSys AG



Learning objective (1):

- To understand the history of Periodic Safety Reports, and the rationale for writing these: ◊ Evolution of PSURs from CIOMS II to ICH, to EU PV legislation ◊ CIOMS V ◊ ICH E2C R1 and R2 ◊ Importance during early post-marketing years ◊ Introduction of DSURs

Learning objective (2):

- To understand the basic structure and rationale behind the contents of PSURs/PBRERs, and DSURs
 - Outline of regulatory requirements
-

1045 - 1055 **Comfort break**

PSURs/PBRERs

1055 - 1155 **Core Safety Information and local datasheets**
Dr Kristina Strutt, MorphoSys AG

◊ Development core safety information ◊ Company core safety information ◊ Listed (PBRER) vs labelled/expected (expedited reporting) ◊ Safety sections in the SmPC

Learning objectives:

To learn the concepts of the company core datasheet, the company core safety information and local datasheets.

1155 - 1200 **Comfort break**

Book your place here: www.dsr.u.org/education-training

Contact us on EandT@dsru.org or 023 8040 8600

Browse our full range of courses at www.dsr.u.org

Prog draft 3 WEB (PBRERs 24)

In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

1200 - 1245	Patient exposure for PSURs/PBRERs Dr Kristina Strutt, MorphoSys AG ◇ Exposure data from clinical trials ◇ Post-marketing exposure data ◇ Practicalities in obtaining exposure data Learning objectives: To discuss sources of exposure data and understand how best to present such data in a PBRER
1245 - 1315	Discussion and questions Led by Kristina Strutt
1315 - 1400	Lunch break
1400 - 1405	Introduction to workshop: Calculation of patient exposure Dr Kristina Strutt, MorphoSys AG
1405 - 1445	Workshop: Calculation of patient exposure (group work) Facilitator: Kristina Strutt Learning objectives: To give you practical experience in calculating patient exposure, both from clinical development and post-marketing, and writing this section of the PBRER
1445 - 1450	Comfort break
1450 - 1535	PSURs/PBRERs: Signal and risk evaluation Dr Kristina Strutt, MorphoSys AG ◇ Links to the Risk Management Plan Learning objectives: To understand the guidance given for the Signal and Risk Evaluation sections of the PBRER
1535 - 1545	Comfort break
1545 - 1550	Introduction to workshop: Signal and risk evaluation Dr Kristina Strutt, MorphoSys AG
1550 - 1700	Workshop: Signal and risk evaluation (group work) Facilitators: Kristina Strutt and Rachna Kasliwal Learning objectives: To give you practical experience in incorporating new interval data on safety signals and risks into the PBRER
1700 - 1715	Discussion and questions Led by Kristina Strutt
1715	End of day one

0845 - 0900 (BST) Registration / Meeting room open

0900 Start of day 2

0900 - 1015



PSURs/PBRERs: Clinical studies
PSURs/PBRERs: Published literature
Rachna Kasliwal, UCB

◇ What to report from studies and published literature? ◇ How to find information on studies
◇ Who to consult over study methodology and findings ◇ Literature search strategies
◇ Obtaining search results ◇ Presentation of literature in PBRERs

Learning objectives:

- To learn the types of studies and published literature which may be suitable for inclusion in a PBRER
 - To understand how to handle clinical studies and published literature in PBRERs.
-

1015 - 1025 Comfort break

1025 - 1115



Benefit evaluation
Integrated benefit-risk analysis
Dr Kristina Strutt, MorphoSys AG

◇ Which benefit information to include ◇ Characterisation of benefits ◇ Benefit-risk context and evaluation

Learning objectives:

To understand the scope of benefit-risk evaluation required in PBRERs, and outline the core principles and steps involved in achieving this

1115 - 1120 Comfort break

1120 - 1200

Planning, writing and reviewing a PBRER
Dr Kristina Strutt, MorphoSys AG

◇ Reporting requirements ◇ 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 practical approaches to planning, writing and reviewing a PBRER

1200 - 1210 Comfort break

1210 - 1310



Reviewing and evaluating a PSUR: the regulator's perspective
Dr Emma Cornforth, MHRA

◇ Key criteria for a high quality PSUR

Learning objectives:

- To understand the regulatory aspects of PSURs – Assessment process; PSUR outcomes; Compliance
 - To obtain an appreciation of regulatory authority expectations
-

1310 - 1400 Lunch break

1400 - 1405	Introduction to workshop: Reviewing a PSUR/PBRER Dr Kristina Strutt, MorphoSys AG
1405 - 1515	Workshop: Reviewing a PSUR/PBRER (group work) Facilitators: Kristina Strutt and TBC Learning objective: To give you practical experience in reviewing sections of a PSUR To further understand the content of Section 16.2 of the PBRER
1515 - 1525	Comfort break
DSURs	
1525 - 1625	Harmonising the production of PSURs and DSURs – a practical approach Dr Kristina Strutt, MorphoSys AG Learning objectives: <ul style="list-style-type: none"> • To understand how the content and preparation of DSURs can overlap with that for PSURs, and the synergies that can be achieved through harmonising the production of these • Practical hints and tips for how to approach this harmonisation
1625 - 1645	Final discussion and questions Led by Kristina Strutt
1645	Close of meeting
1645 - 1700	Postgraduate in Pharmacovigilance students only Student Voice meeting to discuss any questions regarding the post-course assignment or postgraduate programme