

DEVELOP  
YOUR SKILLS

IMPROVE YOUR  
CAREER

REALISE YOUR  
POTENTIAL

EXPAND YOUR  
KNOWLEDGE



Drug Safety Research Unit

## Assessment and Medical Evaluation of Individual Case Safety Reports

Novotel London West Hotel, Hammersmith, London

16 - 17 October 2019

Chairperson: Zeshan Iqbal

Wednesday 16 October

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**0815 - 0845**    **Registration for delegates**

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**0845 – 0900**    **Introduction to the course**  
Zeshan Iqbal, Kinapse

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**0900 – 0930**    **Regulatory requirements for ICSRs, principles/definitions**  
Rhian McNaughton, Eli Lilly

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**0930 – 1045**    **Medical review, company causality and seriousness assessments  
(Including practical session)**  
Presentation: Ennis Lee, Independent Consultant  
Practical session facilitators: Ennis Lee & Zeshan Iqbal

*◇Spontaneous, Other solicited sources (Compassionate use and NISs) and Interventional studies*

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**1045 - 1100**    **Coffee**

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**1100 – 1215**    **Special Situations**  
Martin Menke, CSL Behring

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**1215 – 1300**    **Special Situations practical session**  
Martin Menke, CSL Behring

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**1300 - 1400**    **Lunch**

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**1400 - 1445**    **Literature and cluster reports**  
Martin Menke, CSL Behring

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**1445 - 1500**    **Tea**

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**1500 - 1600**    **Practical session on literature and cluster reports**  
Facilitator: Martin Menke, CSL Behring

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**1600 - 1630**    **Question & Answer session**  
Led by Zeshan Iqbal

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**1630**            **End of day one**

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**0830 - 0845**    **Registration**

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**0830 – 0845**    **Postgraduate in Pharmacovigilance students only**  
Student meeting

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**0845**            **Start of day 2**

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**0845 - 0930**    **MedDRA coding**  
Jane Knight, MedDRA

*◇The importance of coding, principles of coding, types of data for coding, specific challenges and practical exercises*

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**0930 - 1030**    **Practical session on MedDRA coding**  
Facilitator: Jane Knight, MedDRA

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**1030 - 1045**    **Coffee**

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**1045 - 1130**    **Company Clinical Comments and Periodic Report comments**  
Zeshan Iqbal, Kinapse

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**1130 - 1230**    **Practical session on narrative writing, company and periodic report comments**  
Facilitator: Zeshan Iqbal

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**1230 - 1315**    **Management and training of third party suppliers**  
Hermone Berhane, Roche

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**1315 - 1400**    **Lunch**

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**1400 - 1500**    **Regulatory reporting and electronic submissions**  
Kendal Harrison, MHRA

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**1500 - 1545**    **Quality reports from regulatory authorities**  
Kendal Harrison, MHRA

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**1545 - 1600**    **Tea**

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**1600 - 1700**    **Practical session on quality reports**  
Facilitator: Zeshan Iqbal

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**1700**            **Close of meeting**

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