DEVELOP YOUR SKILLS

IMPROVE YOUR CAREER

REALISE YOUR POTENTIAL

EXPAND YOUR KNOWLEDGE

Drug Safety Research Unit

Monitoring Safety in Clinical Trials and Drug Development

Novotel London West Hotel, Hammersmith, London

29 – 30 January 2020

Wednesday 29 January

0845 - 0915	**Registration for delegates**
0915 – 0930	**Introduction to the meeting**
0930 – 1015	**Regulatory framework for clinical trials**
1015 – 1115	**Development of labelling from DCSI to CCSI and the SPC**
1115 - 1130	**Coffee**
1130 – 1315	**Developmental Risk Management Plans – The challenges (presentation & interactive session)**
1315 - 1415	**Lunch**
1415 - 1500	**A practical approach to pharmacovigilance in clinical trials**
1500 - 1515	**Tea**
1515 - 1600	**Monitoring safety with an investigational agent in co-development partnerships**

Book your place here: https://www.dsru.org/education-training/
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1600 - 1700	**Open interactive Session - Topics for speaker/delegate discussion and debate**
1700	**End of day one**
1700 - 1800	**Postgraduate in Pharmacovigilance students only** Presentations to be given by delegates attending this course as Postgraduate students

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Thursday 30 January

0900 - 0915	**Registration**
0900 – 0915	**Postgraduate in Pharmacovigilance students only** Student meeting
0915	**Start of day 2**
0915 – 1015	**Communication of safety information for the protection of the trial population (presentation & interactive session)**
1015 - 1100	**Premarketing drug safety: some thoughts and practical implications**
1100 - 1115	**Coffee**
1115 - 1230	**Pharmacovigilance in GCP inspections**
1230 - 1300	**Data Safety Monitoring Boards**
1300 - 1400	**Lunch**

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1400 - 1445	**PAES / PASS**
1445 - 1530	**Clinical Trial Regulation – Safety Reporting** What we know and foreseen challenges
1530 - 1545	**Tea**
1545 - 1700	**Background and implementation of Developmental Safety Update Reports**
1700 - 1715	**Final questions**
1715	**Close of meeting**

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