

**MONITORING SAFETY IN CLINICAL TRIALS & DRUG DEVELOPMENT
LONDON
FEBRUARY 2013**

PROGRAMME – Wednesday

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 – 1215	A practical approach to pharmacovigilance in clinical trials
1215 - 1315	Lunch
1315 – 1400	Premarketing drug safety: some thoughts and practical implications
1400 – 1430	Data Safety Monitoring Boards
1430 – 1445	Tea
1445 - 1530	Monitoring safety with an investigational agent in co-development partnerships
1530 – 1630	Open Interactive Session - Topics for speaker/delegate discussion and debate
<i>1630 – 1700</i>	<i>Postgraduate in Pharmacovigilance students only Presentations to be given by delegates attending this course as Postgraduate students</i>
1845	Complimentary course dinner

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PROGRAMME – Thursday

0900 – 0915	Registration for delegates
0915 – 1000	Reporting to EudraVigilance Clinical Trial Module – practicalities and challenges
1000 - 1100	Background and Implementation of the Developmental Safety Update Report
1100 - 1115	Coffee
1115 – 1245	Developmental Risk Management Plans – The challenges (presentation & interactive session)
1245 – 1345	Lunch
1345 – 1445	Communication of safety information for the protection of the trial population (Presentation & interactive session)
1445 - 1530	Pharmacovigilance in GCP inspections
1530 - 1545	Tea
1545 - 1615	Open Interactive Session - Topics for speaker/delegate discussion and debate
1615	Close of meeting