

RISK BENEFIT ASSESSMENT IN PHARMACOVIGILANCE

14 - 15 OCTOBER 2009

Solent Hotel, Whiteley, near Fareham, Hampshire

PROGRAMME – 14 October

- 0830 - 0850** **Registration for delegates**
- 0850 - 0900** **Welcome and introduction to the course**
- 0900 - 1015** **Risk-Benefit Assessment – DSS 6**
Basic principles of risk; Definitions and aspects of methods
Teaching objectives: To introduce candidates to the risk assessment, risk management cycle and also CIOMS IV. To provide an outline as to how risk may be evaluated statistically and otherwise. To discuss the factors of level of, and number of, patients being exposed.
• Risk identification • Risk analysis • Prioritisation of risk • Risk resolution • Risk monitoring • Basic pharmacoepidemiology • Causality • CIOMS IV proposals • Evidence-based medicine • Measures of association • Concept of Relative Risk, Number needed to harm, Odds ratio and other parameters
- 1015 - 1030** **Coffee**
- 1030 - 1115** **Sources of safety data – DSS 4 & DSS 5**
Teaching objective: To guide the candidates as to where to look for signals and how to prioritise what you find and also how to trawl for further information in case series.
• Definitions • Literature sources (actual drug/class reports) • Internal/external research • Commercial partners • Spontaneous • Legal • Regulatory • Licensing agreements
- 1115 - 1200** **Drafting safety information documents – DSS 3, DSS 7 & DSS 8**
Teaching objective: To illustrate the safety sections in the SmPC and the PIL, showing what sections have safety implications and the number of places in which ambiguities may arise due to inevitable replication (especially in the SmPC). To enable candidates to be able to understand the CCSI and how it differs from regional data sheet safety information.
• SPC • PIL • CSI • External communications
- 1200 – 1300** **Lunch**
- 1300 - 1400** **Interactive Session: HMT/PMST Candidates' Risk Benefit Presentations/Discussions DSS 5**
- 1400 - 1430** **Risk management - the studies – DSS 6**
Teaching objective: To provide the course members with an understanding of Pharmacovigilance Planning and the studies which are required for Risk Management
• The data sources for Risk Management planning • How to integrate the Risk Management Plan • The studies to understand the epidemiology of disease and the incidence of adverse events in the underlying population • Studies to examine early safety signals • Studies to monitor the release of products to larger populations

1430 - 1515

Risk management – taking action - DSS 7, DSS 8 & DSS 9

Teaching objective: To provide the course members with an understanding of the different activities which may be undertaken to manage and minimise known risks (i.e. risk resolution)

- *How can risks with medicines be minimised?*
- *Risk management programmes*
- *Regulatory actions*
- *Amending product information*
- *Letters to Health Professionals*
- *Press releases/Media*
- *Choosing between the options*
- *Assessing urgency – what is a crisis?*

1515 – 1530

Tea

1530 – 1715

Workshop: Making risk-benefit judgements DSS5 & DSS 6

Teaching objective: To illustrate the challenges of making risk-benefit judgements at the population level using high level information for three topical and important issues

- *Judge the overall balance of risks and benefits*
- *Consider in what circumstances the risk-benefit could be judged positive*
- *Propose studies and measures aimed at maximising the balance of benefit and risk*

1900

Complimentary course dinner

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0845 – 0900

Registration for day 2

0900 - 0945

Overview of regulations and guidelines governing risk benefit (ICH, EMEA, CPMP, FDA) - DSS 2 & DSS 3

Teaching objective: To introduce the candidate to the plethora of regulations and guidelines that govern identifying, analysing, prioritising and monitoring risk.

- *CIOMS IV* • *IB (DCSI) Annual updates (IB, Clinical Trials Directive, IND)* • *Common Technical Document* • *ICH clinical safety guidelines (including PSURs)* • *CPMP/FDA guidelines* • *FDA including PDUFA III*

0945 – 1030

Practical implications of completing regulatory requirements - DSS 2, DSS 3 & DSS 4

Teaching objective: To ensure the practical aspects of implementing regulations and guidelines are understood. To ensure candidates are aware of resource and time implications for planning safety reporting including providing tips for planning and for making such activities more efficient.

- *SOPs and compliance* • *Annual updates for clinical trial programmes* • *Templates for documents* • *Timetabling and planning* • *Cross functional teams* • *QA and compliance* • *Routine ADR reporting and unexpected events – how often and when do I need to do something*

1030 – 1045

Discussion

1045 – 1100

Coffee

1100 - 1230

Workshop: Crisis management - DSS 7, DSS 8 & DSS 9

Teaching objective: To illustrate the challenges faced in a major drug safety crisis and help participants understand the principles for (1) deciding what actions should be taken (2) successfully managing a crisis.

1230 – 1330

Lunch

1330 – 1415

Periodic Safety Update Reports - DSS 3

Teaching objective: To introduce course participants to the history of PSURs and rationale for writing PSURs.

- *Evolution of PSURs from CIOMS II to ICH* • *Importance during early postmarketing years* • *ICH E2C and addendum*

1415 – 1545

Workshop: Communication of safety issues - DSS 8 & DSS 9

Teaching objective: To give course members an understanding of the principles and practical issues involved in communicating successfully about a major drug safety concern. Participants will be given information based on a real-life issue and asked to (1) develop a communication plan (2) produce a draft letter to health professionals.

1545 - 1600

Tea

1600 – 1645

Risk Benefit Evaluation – bringing it all together

Teaching objective: To link all aspects of Risk Benefit evaluation and illustrate the co-ordination that is required at all levels, i.e. data, data collection, evaluation and decision making.

1645

Close