



Update on SMQs

**MedDRA User Group Meeting
30 June 2005
Washington, DC, USA**

MedDRA® is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)



Recent SMQ Developments

- Meetings:
 - Last meeting May 2005 in Berlin, Germany
 - Next meeting August 2005 in London, UK
- Ten new SMQs to go into phase II this summer
- Seven new SMQs topics assigned to development teams
- Renewal of MoU with CIOMS
- DIA webinar (4 May 2005)



New SMQs

- In production:
 - *Rhabdomyolysis/myopathy*
 - *Torsade de pointes/QT prolongation*
 - *Acute renal failure*
 - *Haemolytic disorders*
 - *Hepatic disorders*
 - *Severe cutaneous adverse reactions*
- In phase II:
 - *Acute pancreatitis*
 - *Agranulocytosis*
 - *Anaphylactic reaction (phase II officially closed 01 April)*
 - *Angioedema*
 - *Asthma/bronchospasm*
 - *Dyslipidaemia*
 - *Haematopoietic cytopenias*
 - *Lack of efficacy/effect*
 - *Lactic acidosis*
 - *Peripheral neuropathy*



New SMQs (cont)

- To phase II (mid 2005):
 - *Drug abuse, dependence and withdrawal*
 - *Haemorrhages*
 - *Hyperglycaemia/new onset diabetes mellitus*
 - *Interstitial lung disease*
 - *Ischaemic heart disease*
 - *Neuroleptic malignant syndrome*
 - *Suicide/depression*
 - *Systemic lupus erythematosus*
 - *Taste and smell disorders*
 - *Vasculitis*
- Assigned:
 - *Biliary disorders*
 - *Cardiomyopathy*
 - *Convulsions*
 - *Dementia*
 - *Encephalopathy*
 - *Pre-malignant lesions*
 - *Shock/circulatory failure*



SMQ Topics (not yet developed)

- *Accidents and injuries*
- *ARDS*
- *Coagulation disorders*
- *Ear disorders*
- *Extrapyramidal disorder*
- *Guillain-Barre syndrome*
- *Hypertension*
- *Hyponatraemia/SIADH*
- *Hypotension*
- *Immune reconstitution syndrome*
- *Immunogenicity*
- *Nephropathy*
- *Nephrotic syndrome*
- *Oedema*
- *Overdose*
- *Pulmonary hypertension*
- *Renal disorders*
- *Respiratory depression*
- *Secondary immunocompromised state*
- *Thrombophlebitis*



Other SMQ Information

- Change in documentation
 - Phase II SMQ Introductory Guide was getting huge
 - For this posting, changed to “bulleted summaries” of original CIOMS WG phase I documentation
 - Links provided if users wish to see original WG phase I documentation
- Fate of Special Search Categories (SSCs)



Questions for MedDRA users...

- What's the difference between an SSC and an SSQ?
- What is the difference between a phase II and production SMQ?
- What is your understanding of the value of phase II testing?
- Do you know what happens to your phase II testing results?
- Do you know how to access phase II SMQs?
Production SMQs?
- For what purpose has your organization used (or plan to use) SMQs?
- Do you know how to have an SMQ topic you'd like develop?

MedDRA®



Questions?