



Standardised MedDRA Queries (SMQs)

MedDRA User Group Meeting
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SMQ Status

- SMQ documentation and initial SMQs are prepared for Phase II testing
 - Rhabdomyolysis/myopathy
 - Torsade de pointes/QT prolongation
- Posted on MSSO website on 10 May 2004
 - Available for download
 - Click on SMQs from main page of MSSO site
 - Core area User ID and Password required



SMQ Status (cont)

- Five additional SMQs are nearing Phase II testing
 - Cardiac failure
 - Hepatic disorders (series of SMQs in a hierarchy)
 - Acute renal failure
 - Haemolytic disorders
 - Severe cutaneous adverse reactions*

(* approved by CIOMS WG May 2004 in Uppsala, Sweden)



SMQs Under Development

- **Haematopoietic cytopenias**
- **Haemorrhages**
- **Interstitial lung disorder**
- **Vasculitis**
- **Acute pancreatitis**
- **Anaphylactic reaction**
- **Lack of effect/efficacy**
- **Neuroleptic malignant syndrome**
- **Suicide/depression**
- **Angioedema**
- **Arrhythmia**
- **Thrombosis/embolism**
- **Lactic acidosis**
- **Retinal disorders**
- **Corneal disorders**
- **Optic nerve disorders**
- **Hyperlipidaemia**
- **Hyperglycaemia**
- **Drug abuse and dependence**
- **Asthma and bronchoconstriction**
- **Peripheral neuropathy**



SMQ Plans 2004

- SMQ Schedule
 - 10 May – Initial 2 SMQs released for Phase II testing
 - Approx. mid-June – Additional SMQs (at least 4; 5 if documentation provided in time to MSSO) released for Phase II testing
 - 1 September – Final date for feedback on initial SMQs
 - November – Feedback presented to MedDRA MB
 - December – March 2005 – Initial set of SMQs available for production use



Future SMQs

Adverse pregnancy outcome

Anaemia

Angina pectoris

Anticholinergic syndrome

ARDS

AV block

Cardiac arrest

Cardiomyopathy

Cerebral infarction

Cerebrovascular disorder

Cholelithiasis

Chronic obstructive pulm. disease

Circulatory failure

Coagulation disorders

Convulsions

Corneal Disorders

Coronary artery disorder

Drug induced lupus erythematosus

Encephalopathy

Extrapyramidal disorder

Heart block greater than 1st degree

Hypertension

Hyponatremia/SIADH

Hypotension

Lupus erythematosus syndrome

Mixed liver injury

Myocardial infarction

Myocardial ischaemia

Nephropathy

Nephrotic syndrome

Oedema

Overdose

Pain

Perforation, Ulcer Bleeding (Gastrointestinal)

Pre-malignant lesions

Pseudomembranous colitis

Pulmonary fibrosis

Pulmonary hypertension

Respiratory depression

Retroperitoneal fibrosis

Secondary immunocompromised state

Serotonin syndrome

Shock

Syncope

Thrombophlebitis

Ventricular Arrhythmias



Discussion points

- Specific uses of SMQs
- Study data and post-marketing data
- Phase II testing (facilitation by feedback form?)
- Future SMQs – topics covered, priority