

**List of SMQ Topics for Development by CIOMS Working Group for SMQs  
(as of 1 September 2019)**

**SMQs in Production**

- Accidents and injuries
- Acute central respiratory depression
- Acute pancreatitis
- Acute renal failure
- Agranulocytosis
- Anaphylactic reaction
- Angioedema
- Anticholinergic syndrome
- Arthritis
- Asthma/bronchospasm
- Biliary disorders
- Breast neoplasms, malignant and unspecified
- Cardiac arrhythmias
- Cardiac failure
- Cardiomyopathy
- Central nervous system vascular disorders
- Chronic kidney disease
- Conjunctival disorders
- Convulsions
- Corneal disorders
- Dehydration
- Dementia
- Demyelination
- Depression and suicide/self-injury
- Drug abuse, dependence and withdrawal
- Drug reaction with eosinophilia and systemic symptoms syndrome
- Dyslipidaemia
- Embolic and thrombotic events
- Eosinophilic pneumonia
- Extrapyrmidal syndrome
- Extravasation events (injections, infusions and implants)
- Fertility disorders
- Gastrointestinal nonspecific inflammation and dysfunctional conditions
- Gastrointestinal perforation, ulceration, haemorrhage or obstruction
- Generalised convulsive seizures following immunisation
- Glaucoma
- Guillain-Barre syndrome
- Haematopoietic cytopenias
- Haemodynamic oedema, effusions and fluid overload
- Haemolytic disorders
- Haemorrhages
- Hearing and vestibular disorders
- Hepatic disorders
- Hostility/aggression
- Hyperglycaemia/new onset diabetes mellitus
- Hypersensitivity
- Hypertension
- Hypoglycaemia
- Hypokalaemia
- Hyponatraemia/SIADH
- Hypotonic-hyponresponsive episode
- Infective pneumonia
- Interstitial lung disease
- Ischaemic colitis
- Ischaemic heart disease
- Lack of efficacy/effect
- Lacrimal disorders
- Lactic acidosis
- Lens disorders
- Lipodystrophy
- Malignancies
- Malignant lymphomas
- Medication errors
- Myelodysplastic syndrome
- Neuroleptic malignant syndrome
- Noninfectious diarrhoea
- Noninfectious encephalitis
- Noninfectious encephalopathy/delirium
- Noninfectious meningitis
- Ocular infections
- Ocular motility disorders

- Optic nerve disorders
- Oropharyngeal disorders
- Osteonecrosis
- Osteoporosis/osteopenia
- Ovarian neoplasms, malignant and unspecified
- Periorbital and eyelid disorders
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Premalignant disorders
- Prostate neoplasms, malignant and unspecified
- Proteinuria
- Pseudomembranous colitis
- Psychosis and psychotic disorders
- Pulmonary hypertension
- Renovascular disorders
- Respiratory failure
- Retinal disorders
- Retroperitoneal fibrosis
- Rhabdomyolysis/myopathy
- Scleral disorders
- Sepsis
- Severe cutaneous adverse reactions
- Shock
- Skin neoplasms, malignant and unspecified
- Systemic lupus erythematosus
- Taste and smell disorders
- Tendinopathies and ligament disorders
- Thrombophlebitis
- Thyroid dysfunction
- Torsade de pointes/QT prolongation
- Tubulointerstitial diseases
- Tumour lysis syndrome
- Uterine and fallopian tube neoplasms, malignant and unspecified
- Vasculitis

### **SMQs in Development/Testing**

- Autoimmune diseases/Immune mediated medical conditions
- Opportunistic infections
- Progressive multifocal leukoencephalopathy