

Adverse events of Special Interest as per Periodic Safety Update Report and Risk Management Plan

MedDRA (v 18.1) terms	Safety risks (RMP)
Candida endophthalmitis	Infectious endophthalmitis
Endophthalmitis	Infectious endophthalmitis
Eye infection	Infectious endophthalmitis
Eye infection fungal	Infectious endophthalmitis
Eye infection intraocular	Infectious endophthalmitis
Eye infection chlamydial	Infectious endophthalmitis
Eye infection bacterial	Infectious endophthalmitis
Hypopyon	Infectious endophthalmitis
Eye infection staphylococcal	Infectious endophthalmitis
Infective uveitis	Infectious endophthalmitis
Mycotic endophthalmitis	Infectious endophthalmitis
Panophthalmitis	Infectious endophthalmitis
Suspected transmission of an infectious agent via product	Infectious endophthalmitis
Viral uveitis	Infectious endophthalmitis
Vitreous abscess	Infectious endophthalmitis
Macular detachment	Retinal detachment and retinal tear (search was performed with and without the LLT serous detachment of macula)
Retinal tear	Retinal detachment and retinal tear (search was performed with and without the LLT serous detachment of macula)
Retinal detachment	Retinal detachment and retinal tear (search was performed with and without the LLT serous detachment of macula)
Retinopexy	Retinal detachment and retinal tear (search was performed with and without the LLT serous detachment of macula)
Scleral buckling surgery	Retinal detachment and retinal tear (search was performed with and without the LLT serous detachment of macula)
Cataract traumatic	Traumatic cataract
Injection site injury	Traumatic cataract
Posterior capsule rupture	Traumatic cataract
Lenticular injury	Traumatic cataract
Acute zonal occult outer retinopathy	Intraocular inflammation
Anterior chamber cell	Intraocular inflammation
Anterior chamber flare	Intraocular inflammation
Anterior chamber fibrin	Intraocular inflammation

Anterior chamber inflammation	Intraocular inflammation
Aqueous fibrin	Intraocular inflammation
Autoimmune uveitis	Intraocular inflammation
Birdshot chorioretinopathy	Intraocular inflammation
Cholesterolosis bulbi	Intraocular inflammation
Chorioretinitis	Intraocular inflammation
Chorioretinopathy	Intraocular inflammation
Choroiditis	Intraocular inflammation
Ciliary hyperemia	Intraocular inflammation
Cogan's syndrome	Intraocular inflammation
Cyclitic membrane	Intraocular inflammation
Cyclitis	Intraocular inflammation
Eye inflammation	Intraocular inflammation
Idiopathic orbital inflammation	Intraocular inflammation
Iridocyclitis	Intraocular inflammation
Iritis	Intraocular inflammation
Macular edema	Intraocular inflammation
Neuromyelitis optica	Intraocular inflammation
Non-infectious endophthalmitis	Intraocular inflammation
Noninfective chorioretinitis	Intraocular inflammation
Noninfective retinitis	Intraocular inflammation
Ocular vasculitis	Intraocular inflammation
Ocular pemphigoid	Intraocular inflammation
Ocular hyperemia	Intraocular inflammation
Ocular sarcoidosis	Intraocular inflammation
Oculomucocutaneous syndrome	Intraocular inflammation
Oculorespiratory syndrome	Intraocular inflammation
Ophthalmia neonatorum	Intraocular inflammation
Optic neuritis	Intraocular inflammation
Periorbital edema	Intraocular inflammation
Pseudoendophthalmitis	Intraocular inflammation
Retinal edema Retinal vasculitis	Intraocular inflammation
Retinitis	Intraocular inflammation
Toxic anterior segment syndrome	Intraocular inflammation
Tubulointerstitial nephritis and uveitis syndrome	Intraocular inflammation
Uveitis	Intraocular inflammation
Uveitis-glaucoma-hyphema syndrome	Intraocular inflammation
Vitritis	Intraocular inflammation
Vogt-Koyanagi-Harada syndrome	Intraocular inflammation
Intraocular pressure increased	Intraocular pressure increase
Intraocular pressure fluctuation	Intraocular pressure increase
Intraocular pressure test abnormal	Intraocular pressure increase
Ocular hypertension	Intraocular pressure increase

Abdominal wall hematoma	Non-ocular hemorrhage
Abnormal withdrawal bleeding	Non-ocular hemorrhage
Abdominal wall hemorrhage	Non-ocular hemorrhage
Adrenal hematoma	Non-ocular hemorrhage
Acute hemorrhagic ulcerative colitis	Non-ocular hemorrhage
Acute hemorrhagic leukoencephalitis	Non-ocular hemorrhage
Adrenal hemorrhage	Non-ocular hemorrhage
Anal hemorrhage	Non-ocular hemorrhage
Anal ulcer hemorrhage	Non-ocular hemorrhage
Anastomotic hemorrhage	Non-ocular hemorrhage
Anastomotic ulcer hemorrhage	Non-ocular hemorrhage
Aneurysm ruptured	Non-ocular hemorrhage
Anorectal varices hemorrhage	Non-ocular hemorrhage
Aortic aneurysm rupture	Non-ocular hemorrhage
Aortic dissection rupture	Non-ocular hemorrhage
Aortic intramural hematoma	Non-ocular hemorrhage
Aortic perforation	Non-ocular hemorrhage
Aortic rupture	Non-ocular hemorrhage
Aponeurosis contusion	Non-ocular hemorrhage
Application site bruise	Non-ocular hemorrhage
Application site hematoma	Non-ocular hemorrhage
Application site hemorrhage	Non-ocular hemorrhage
Arterial hemorrhage	Non-ocular hemorrhage
Arterial intramural hematoma	Non-ocular hemorrhage
Arterial perforation	Non-ocular hemorrhage
Arterial rupture	Non-ocular hemorrhage
Arteriovenous fistula site hematoma	Non-ocular hemorrhage
Arteriovenous fistula site hemorrhage	Non-ocular hemorrhage
Arteriovenous graft site hematoma	Non-ocular hemorrhage
Arteriovenous graft site hemorrhage	Non-ocular hemorrhage
Astringent therapy	Non-ocular hemorrhage
Atrial rupture	Non-ocular hemorrhage
Auricular hematoma	Non-ocular hemorrhage
Basilar artery perforation	Non-ocular hemorrhage
Basal ganglia hemorrhage	Non-ocular hemorrhage
Basal ganglia hematoma	Non-ocular hemorrhage
Bladder tamponade	Non-ocular hemorrhage
Bleeding varicose vein	Non-ocular hemorrhage
Blood blister	Non-ocular hemorrhage
Blood urine	Non-ocular hemorrhage
Blood urine present	Non-ocular hemorrhage
Bloody discharge	Non-ocular hemorrhage
Bloody peritoneal effluent	Non-ocular hemorrhage
Bone contusion	Non-ocular hemorrhage

Bone marrow hemorrhage	Non-ocular hemorrhage
Brain stem hematoma	Non-ocular hemorrhage
Brain stem hemorrhage	Non-ocular hemorrhage
Breast hematoma	Non-ocular hemorrhage
Breast hemorrhage	Non-ocular hemorrhage
Broad ligament hematoma	Non-ocular hemorrhage
Bronchial hemorrhage	Non-ocular hemorrhage
Cardiac contusion	Non-ocular hemorrhage
Carotid artery perforation	Non-ocular hemorrhage
Catheter site bruise	Non-ocular hemorrhage
Carotid aneurysm rupture	Non-ocular hemorrhage
Catheter site hematoma	Non-ocular hemorrhage
Catheter site hemorrhage	Non-ocular hemorrhage
Central nervous system hemorrhage	Non-ocular hemorrhage
Cephalhematoma	Non-ocular hemorrhage
Cerebellar hematoma	Non-ocular hemorrhage
Cerebellar hemorrhage	Non-ocular hemorrhage
Cerebral aneurysm ruptured syphilitic	Non-ocular hemorrhage
Cerebral arteriovenous malformation hemorrhagic	Non-ocular hemorrhage
Cerebral artery perforation	Non-ocular hemorrhage
Cerebral hematoma	Non-ocular hemorrhage
Cerebral hemorrhage	Non-ocular hemorrhage
Cerebral hemorrhage fetal	Non-ocular hemorrhage
Cerebral hemorrhage neonatal	Non-ocular hemorrhage
Cervix hematoma uterine	Non-ocular hemorrhage
Cervix hemorrhage uterine	Non-ocular hemorrhage
Cerebral microhemorrhage	Non-ocular hemorrhage
Chronic gastrointestinal bleeding	Non-ocular hemorrhage
Chronic pigmented purpura	Non-ocular hemorrhage
Coital bleeding	Non-ocular hemorrhage
Colonic hematoma	Non-ocular hemorrhage
Contusion	Non-ocular hemorrhage
Cullen's sign	Non-ocular hemorrhage
Cystitis hemorrhagic	Non-ocular hemorrhage
Deep dissecting hematoma	Non-ocular hemorrhage
Diarrhea hemorrhagic	Non-ocular hemorrhage
Disseminated intravascular coagulation	Non-ocular hemorrhage
Duodenal ulcer hemorrhage	Non-ocular hemorrhage
Diverticulum intestinal hemorrhagic	Non-ocular hemorrhage
Diverticulitis intestinal haemorrhagic	Non-ocular hemorrhage
Duodenitis hemorrhagic	Non-ocular hemorrhage
Dysfunctional uterine bleeding	Non-ocular hemorrhage
Ear hemorrhage	Non-ocular hemorrhage

Ecchymosis	Non-ocular hemorrhage
Epidural hemorrhage	Non-ocular hemorrhage
Enterocolitis hemorrhagic	Non-ocular hemorrhage
Encephalitis hemorrhagic	Non-ocular hemorrhage
Epistaxis	Non-ocular hemorrhage
Exsanguination	Non-ocular hemorrhage
Extradural hematoma	Non-ocular hemorrhage
Extravasation blood	Non-ocular hemorrhage
Femoral artery perforation	Non-ocular hemorrhage
Femoral vein perforation	Non-ocular hemorrhage
Fetal-maternal haemorrhage	Non-ocular hemorrhage
Gastric hemorrhage	Non-ocular hemorrhage
Gastric ulcer hemorrhage	Non-ocular hemorrhage
Gastric ulcer hemorrhage, obstructive	Non-ocular hemorrhage
Gastric varices hemorrhage	Non-ocular hemorrhage
Gastritis alcoholic hemorrhagic	Non-ocular hemorrhage
Gastritis hemorrhagic	Non-ocular hemorrhage
Gastroduodenal hemorrhage	Non-ocular hemorrhage
Gastroduodenitis hemorrhagic	Non-ocular hemorrhage
Gastrointestinal angiodysplasia hemorrhagic	Non-ocular hemorrhage
Gastrointestinal hemorrhage	Non-ocular hemorrhage
Genital contusion	Non-ocular hemorrhage
Gastrointestinal ulcer hemorrhage	Non-ocular hemorrhage
Gastrointestinal polyp hemorrhage	Non-ocular hemorrhage
Genital hemorrhage	Non-ocular hemorrhage
Hemarthrosis	Non-ocular hemorrhage
Grey Turner's sign	Non-ocular hemorrhage
Graft hemorrhage	Non-ocular hemorrhage
Gingival bleeding	Non-ocular hemorrhage
Hematoma	Non-ocular hemorrhage
Hematocoele	Non-ocular hemorrhage
Hematochezia	Non-ocular hemorrhage
Hematemesis	Non-ocular hemorrhage
Hematoma evacuation	Non-ocular hemorrhage
Hematoma infection	Non-ocular hemorrhage
Hematosalpinx	Non-ocular hemorrhage
Hemospermia	Non-ocular hemorrhage
Hematotympanum	Non-ocular hemorrhage
Hematuria	Non-ocular hemorrhage
Hematuria traumatic	Non-ocular hemorrhage
Hemobilia	Non-ocular hemorrhage
Hemophilic arthropathy	Non-ocular hemorrhage
Hemoptysis	Non-ocular hemorrhage

Hemorrhage	Non-ocular hemorrhage
Hemorrhage coronary artery	Non-ocular hemorrhage
Hemorrhage fetal	Non-ocular hemorrhage
Hemorrhage neonatal	Non-ocular hemorrhage
Hemorrhage intracranial	Non-ocular hemorrhage
Hemorrhagic anemia	Non-ocular hemorrhage
Hemorrhage urinary tract	Non-ocular hemorrhage
Hemorrhage subepidermal	Non-ocular hemorrhage
Hemorrhage in pregnancy	Non-ocular hemorrhage
Hemorrhage subcutaneous	Non-ocular hemorrhage
Hemorrhagic arteriovenous malformation	Non-ocular hemorrhage
Hemorrhagic ascites	Non-ocular hemorrhage
Hemorrhagic cerebral infarction	Non-ocular hemorrhage
Hemorrhagic cyst	Non-ocular hemorrhage
Hemorrhagic diathesis	Non-ocular hemorrhage
Hemorrhagic disease of newborn	Non-ocular hemorrhage
Hemorrhagic disorder	Non-ocular hemorrhage
Hemorrhagic erosive gastritis	Non-ocular hemorrhage
Hemorrhagic hepatic cyst	Non-ocular hemorrhage
Hemorrhagic infarction	Non-ocular hemorrhage
Hemorrhagic necrotic pancreatitis	Non-ocular hemorrhage
Hemorrhagic ovarian cyst	Non-ocular hemorrhage
Hemorrhagic stroke	Non-ocular hemorrhage
Hemorrhagic thyroid cyst	Non-ocular hemorrhage
Hemorrhagic transformation stroke	Non-ocular hemorrhage
Hemorrhagic tumour necrosis	Non-ocular hemorrhage
Hemorrhagic urticaria	Non-ocular hemorrhage
Hemorrhagic vasculitis	Non-ocular hemorrhage
Hemorrhoidal hemorrhage	Non-ocular hemorrhage
Hemostasis	Non-ocular hemorrhage
Hemothorax	Non-ocular hemorrhage
Henoch-Schonlein purpura	Non-ocular hemorrhage
Hepatic hemangioma rupture	Non-ocular hemorrhage
Hepatic hematoma	Non-ocular hemorrhage
Hepatic hemorrhage	Non-ocular hemorrhage
Hereditary hemorrhagic telangiectasia	Non-ocular hemorrhage
Hyperfibrinolysis	Non-ocular hemorrhage
Iliac artery perforation	Non-ocular hemorrhage
Iliac artery rupture	Non-ocular hemorrhage
Iliac vein perforation	Non-ocular hemorrhage
Immune thrombocytopenic purpura	Non-ocular hemorrhage
Implant site bruising	Non-ocular hemorrhage
Implant site hematoma	Non-ocular hemorrhage

Implant site hemorrhage	Non-ocular hemorrhage
Incision site hematoma	Non-ocular hemorrhage
Incision site hemorrhage	Non-ocular hemorrhage
Increased tendency to bruise	Non-ocular hemorrhage
Infusion site bruising	Non-ocular hemorrhage
Inferior vena cava perforation	Non-ocular hemorrhage
Induced abortion hemorrhage	Non-ocular hemorrhage
Internal hemorrhage	Non-ocular hemorrhage
Instillation site hemorrhage	Non-ocular hemorrhage
Instillation site hematoma	Non-ocular hemorrhage
Infusion site hemorrhage	Non-ocular hemorrhage
Infusion site hematoma	Non-ocular hemorrhage
Intestinal hematoma	Non-ocular hemorrhage
Intestinal haemorrhage	Non-ocular hemorrhage
Intra-abdominal hematoma	Non-ocular hemorrhage
Intra-abdominal hemorrhage	Non-ocular hemorrhage
Intracerebral hematoma evacuation	Non-ocular hemorrhage
Intracranial hematoma	Non-ocular hemorrhage
Intracranial tumour hemorrhage	Non-ocular hemorrhage
Intrapartum hemorrhage	Non-ocular hemorrhage
Intraventricular hemorrhage	Non-ocular hemorrhage
Intraventricular hemorrhage neonatal	Non-ocular hemorrhage
Kidney contusion	Non-ocular hemorrhage
Large intestinal hemorrhage	Non-ocular hemorrhage
Large intestinal ulcer hemorrhage	Non-ocular hemorrhage
Laryngeal hematoma	Non-ocular hemorrhage
Laryngeal hemorrhage	Non-ocular hemorrhage
Lip hematoma	Non-ocular hemorrhage
Lip hemorrhage	Non-ocular hemorrhage
Liver contusion	Non-ocular hemorrhage
Lower gastrointestinal hemorrhage	Non-ocular hemorrhage
Lower limb artery perforation	Non-ocular hemorrhage
Mallory-Weiss syndrome	Non-ocular hemorrhage
Lymph node hemorrhage	Non-ocular hemorrhage
Melena	Non-ocular hemorrhage
Mediastinal hemorrhage	Non-ocular hemorrhage
Mediastinal hematoma	Non-ocular hemorrhage
Melena neonatal	Non-ocular hemorrhage
Meningorrhagia	Non-ocular hemorrhage
Menometrorrhagia	Non-ocular hemorrhage
Menorrhagia	Non-ocular hemorrhage
Mesenteric hematoma	Non-ocular hemorrhage
Metrorrhagia	Non-ocular hemorrhage
Mesenteric haemorrhage	Non-ocular hemorrhage

Mouth hemorrhage	Non-ocular hemorrhage
Mucocutaneous hemorrhage	Non-ocular hemorrhage
Mucosal haemorrhage	Non-ocular hemorrhage
Muscle contusion	Non-ocular hemorrhage
Muscle hemorrhage	Non-ocular hemorrhage
Myocardial hemorrhage	Non-ocular hemorrhage
Myocardial rupture	Non-ocular hemorrhage
Nevus hemorrhage	Non-ocular hemorrhage
Nail bed bleeding	Non-ocular hemorrhage
Nasal septum hematoma	Non-ocular hemorrhage
Neonatal gastrointestinal hemorrhage	Non-ocular hemorrhage
Nephritis hemorrhagic	Non-ocular hemorrhage
Nipple exudate bloody	Non-ocular hemorrhage
Esophageal hemorrhage	Non-ocular hemorrhage
Esophagitis hemorrhagic	Non-ocular hemorrhage
Esophageal varices hemorrhage	Non-ocular hemorrhage
Esophageal ulcer hemorrhage	Non-ocular hemorrhage
Oral mucosa hematoma	Non-ocular hemorrhage
Osteorrhagia	Non-ocular hemorrhage
Palpable purpura	Non-ocular hemorrhage
Ovarian hemorrhage	Non-ocular hemorrhage
Ovarian hematoma	Non-ocular hemorrhage
Pancreatic hemorrhage	Non-ocular hemorrhage
Pancreatitis hemorrhagic	Non-ocular hemorrhage
Parathyroid hemorrhage	Non-ocular hemorrhage
Paranasal sinus hematoma	Non-ocular hemorrhage
Papillary muscle hemorrhage	Non-ocular hemorrhage
Parotid gland hemorrhage	Non-ocular hemorrhage
Pelvic hematoma	Non-ocular hemorrhage
Pelvic hematoma obstetric	Non-ocular hemorrhage
Pelvic hemorrhage	Non-ocular hemorrhage
Penile hemorrhage	Non-ocular hemorrhage
Penile hematoma	Non-ocular hemorrhage
Perineal hematoma	Non-ocular hemorrhage
Pericardial hemorrhage	Non-ocular hemorrhage
Penile contusion	Non-ocular hemorrhage
Peptic ulcer hemorrhage	Non-ocular hemorrhage
Peripartum hemorrhage	Non-ocular hemorrhage
Perirenal hematoma	Non-ocular hemorrhage
Peritoneal hemorrhage	Non-ocular hemorrhage
Peritoneal hematoma	Non-ocular hemorrhage
Periventricular hemorrhage neonatal	Non-ocular hemorrhage
Petechiae	Non-ocular hemorrhage
Pharyngeal hematoma	Non-ocular hemorrhage

Pituitary hemorrhage	Non-ocular hemorrhage
Pharyngeal hemorrhage	Non-ocular hemorrhage
Placenta praevia hemorrhage	Non-ocular hemorrhage
Polymenorrhagia	Non-ocular hemorrhage
Post procedural hematuria	Non-ocular hemorrhage
Post procedural hematoma	Non-ocular hemorrhage
Post procedural contusion	Non-ocular hemorrhage
Post abortion hemorrhage	Non-ocular hemorrhage
Post procedural hemorrhage	Non-ocular hemorrhage
Post transfusion purpura	Non-ocular hemorrhage
Postmenopausal hemorrhage	Non-ocular hemorrhage
Postpartum hemorrhage	Non-ocular hemorrhage
Premature separation of placenta	Non-ocular hemorrhage
Procedural hemorrhage	Non-ocular hemorrhage
Proctitis hemorrhagic	Non-ocular hemorrhage
Prostatic hemorrhage	Non-ocular hemorrhage
Pulmonary alveolar hemorrhage	Non-ocular hemorrhage
Pulmonary hemorrhage	Non-ocular hemorrhage
Pulmonary hematoma	Non-ocular hemorrhage
Pulmonary contusion	Non-ocular hemorrhage
Puncture site hemorrhage	Non-ocular hemorrhage
Purpura	Non-ocular hemorrhage
Purpura fulminans	Non-ocular hemorrhage
Purpura neonatal	Non-ocular hemorrhage
Purpura non-thrombocytopenic	Non-ocular hemorrhage
Purpura senile	Non-ocular hemorrhage
Putamen hemorrhage	Non-ocular hemorrhage
Radiation associated hemorrhage	Non-ocular hemorrhage
Rectal hemorrhage	Non-ocular hemorrhage
Renal hematoma	Non-ocular hemorrhage
Renal cyst hemorrhage	Non-ocular hemorrhage
Renal artery perforation	Non-ocular hemorrhage
Scrotal haematocoele	Non-ocular hemorrhage
Rectal ulcer haemorrhage	Non-ocular hemorrhage
Renal hemorrhage	Non-ocular hemorrhage
Respiratory tract hemorrhage	Non-ocular hemorrhage
Respiratory tract hemorrhage neonatal	Non-ocular hemorrhage
Ruptured cerebral aneurysm	Non-ocular hemorrhage
Retroplacental hematoma	Non-ocular hemorrhage
Retroperitoneal hemorrhage	Non-ocular hemorrhage
Retroperitoneal hematoma	Non-ocular hemorrhage
Skin hemorrhage	Non-ocular hemorrhage
Shock hemorrhagic	Non-ocular hemorrhage
Scrotal hematoma	Non-ocular hemorrhage

Skin neoplasm bleeding	Non-ocular hemorrhage
Skin ulcer hemorrhage	Non-ocular hemorrhage
Small intestinal hemorrhage	Non-ocular hemorrhage
Small intestinal ulcer hemorrhage	Non-ocular hemorrhage
Soft tissue hemorrhage	Non-ocular hemorrhage
Spermatocord hemorrhage	Non-ocular hemorrhage
Spinal epidural hematoma	Non-ocular hemorrhage
Spinal cord hemorrhage	Non-ocular hemorrhage
Spinal cord hematoma	Non-ocular hemorrhage
Spinal epidural hemorrhage	Non-ocular hemorrhage
Spinal subarachnoid hemorrhage	Non-ocular hemorrhage
Spleen contusion	Non-ocular hemorrhage
Spinal subdural hemorrhage	Non-ocular hemorrhage
Spinal subdural hematoma	Non-ocular hemorrhage
Splenic artery perforation	Non-ocular hemorrhage
Splenic hematoma	Non-ocular hemorrhage
Splenic hemorrhage	Non-ocular hemorrhage
Splenic varices hemorrhage	Non-ocular hemorrhage
Splinter hemorrhages	Non-ocular hemorrhage
Stoma site hemorrhage	Non-ocular hemorrhage
Spontaneous hemorrhage	Non-ocular hemorrhage
Spontaneous hematoma	Non-ocular hemorrhage
Subarachnoid hemorrhage	Non-ocular hemorrhage
Subarachnoid hematoma	Non-ocular hemorrhage
Stomatitis hemorrhagic	Non-ocular hemorrhage
Subarachnoid hemorrhage neonatal	Non-ocular hemorrhage
Subdural hematoma	Non-ocular hemorrhage
Subcutaneous hematoma	Non-ocular hemorrhage
Subclavian vein perforation	Non-ocular hemorrhage
Subclavian artery perforation	Non-ocular hemorrhage
Subchorionic hemorrhage	Non-ocular hemorrhage
Subchorionic hematoma	Non-ocular hemorrhage
Subdural hematoma evacuation	Non-ocular hemorrhage
Subdural hemorrhage	Non-ocular hemorrhage
Subdural hemorrhage neonatal	Non-ocular hemorrhage
Subgaleal hematoma	Non-ocular hemorrhage
Superior vena cava perforation	Non-ocular hemorrhage
Testicular hemorrhage	Non-ocular hemorrhage
Thalamus hemorrhage	Non-ocular hemorrhage
Third stage postpartum hemorrhage	Non-ocular hemorrhage
Thoracic hemorrhage	Non-ocular hemorrhage
Thrombocytopenic purpura	Non-ocular hemorrhage
Thrombotic thrombocytopenic purpura	Non-ocular hemorrhage
Tonsillar hemorrhage	Non-ocular hemorrhage

Tongue hemorrhage	Non-ocular hemorrhage
Tongue hematoma	Non-ocular hemorrhage
Tracheal hemorrhage	Non-ocular hemorrhage
Tooth socket hemorrhage	Non-ocular hemorrhage
Thyroid hemorrhage	Non-ocular hemorrhage
Tooth pulp hemorrhage	Non-ocular hemorrhage
Traumatic hemothorax	Non-ocular hemorrhage
Traumatic hemorrhage	Non-ocular hemorrhage
Traumatic hematoma	Non-ocular hemorrhage
Traumatic intracranial hemorrhage	Non-ocular hemorrhage
Tumour hemorrhage	Non-ocular hemorrhage
Ulcer hemorrhage	Non-ocular hemorrhage
Umbilical cord hemorrhage	Non-ocular hemorrhage
Umbilical hematoma	Non-ocular hemorrhage
Umbilical hemorrhage	Non-ocular hemorrhage
Upper gastrointestinal hemorrhage	Non-ocular hemorrhage
Ureteric hemorrhage	Non-ocular hemorrhage
Urethral hemorrhage	Non-ocular hemorrhage
Urinary bladder hemorrhage	Non-ocular hemorrhage
Urogenital hemorrhage	Non-ocular hemorrhage
Uterine hematoma	Non-ocular hemorrhage
Uterine hemorrhage	Non-ocular hemorrhage
Vaccination site bruising	Non-ocular hemorrhage
Vaginal hematoma	Non-ocular hemorrhage
Vaccination site hemorrhage	Non-ocular hemorrhage
Vaccination site hematoma	Non-ocular hemorrhage
Vaginal hemorrhage	Non-ocular hemorrhage
Varicose vein ruptured	Non-ocular hemorrhage
Vascular pseudoaneurysm ruptured	Non-ocular hemorrhage
Vascular purpura	Non-ocular hemorrhage
Vein rupture	Non-ocular hemorrhage
Vascular rupture	Non-ocular hemorrhage
Venous hemorrhage	Non-ocular hemorrhage
Venous perforation	Non-ocular hemorrhage
Ventricle rupture	Non-ocular hemorrhage
Vertebral artery perforation	Non-ocular hemorrhage
Vessel puncture site bruise	Non-ocular hemorrhage
Vessel puncture site hemorrhage	Non-ocular hemorrhage
Vulval hematoma	Non-ocular hemorrhage
Vessel puncture site hematoma	Non-ocular hemorrhage
Vulval hematoma evacuation	Non-ocular hemorrhage
Vulval hemorrhage	Non-ocular hemorrhage
Wound hemorrhage	Non-ocular hemorrhage
Wound hematoma	Non-ocular hemorrhage

Capsular warning syndrome	Non-myocardial arterial thromboembolic events
Carotid artery bypass	Non-myocardial arterial thromboembolic events
Carotid arteriosclerosis	Non-myocardial arterial thromboembolic events
Carotid artery stenosis	Non-myocardial arterial thromboembolic events
Carotid arterial embolus	Non-myocardial arterial thromboembolic events
Carotid artery disease	Non-myocardial arterial thromboembolic events
Carotid artery insufficiency	Non-myocardial arterial thromboembolic events
Carotid artery restenosis	Non-myocardial arterial thromboembolic events
Carotid artery perforation	Non-myocardial arterial thromboembolic events
Carotid artery occlusion	Non-myocardial arterial thromboembolic events
Carotid artery stent insertion	Non-myocardial arterial thromboembolic events
Carotid artery thrombosis	Non-myocardial arterial thromboembolic events
Carotid artery stent removal	Non-myocardial arterial thromboembolic events
Carotid endarterectomy	Non-myocardial arterial thromboembolic events
Carotid revascularization	Non-myocardial arterial thromboembolic events
Central nervous system hemorrhage	Non-myocardial arterial thromboembolic events
Cerebellar embolism	Non-myocardial arterial thromboembolic events
Cerebellar artery thrombosis	Non-myocardial arterial thromboembolic events
Cerebellar artery occlusion	Non-myocardial arterial thromboembolic events
Cerebellar hematoma	Non-myocardial arterial thromboembolic events
Cerebellar hemorrhage	Non-myocardial arterial thromboembolic events
Cerebellar infarction	Non-myocardial arterial thromboembolic events
Cerebellar ischemia	Non-myocardial arterial thromboembolic events
Cerebellar microhemorrhage	Non-myocardial arterial thromboembolic events
Cerebral aneurysm perforation	Non-myocardial arterial thromboembolic events
Cerebral aneurysm ruptured syphilitic	Non-myocardial arterial thromboembolic events
Cerebral arteriosclerosis	Non-myocardial arterial thromboembolic events
Cerebral arteriovenous malformation hemorrhagic	Non-myocardial arterial thromboembolic events
Cerebral artery stenosis	Non-myocardial arterial thromboembolic events
Cerebral artery restenosis	Non-myocardial arterial thromboembolic events
Cerebral artery perforation	Non-myocardial arterial thromboembolic events
Cerebral artery occlusion	Non-myocardial arterial thromboembolic events
Cerebral artery embolism	Non-myocardial arterial thromboembolic events
Cerebral artery thrombosis	Non-myocardial arterial thromboembolic events
Cerebral gas embolism	Non-myocardial arterial thromboembolic events
Cerebral hematoma	Non-myocardial arterial thromboembolic events
Cerebral hemorrhage	Non-myocardial arterial thromboembolic events
Cerebral hemorrhage foetal	Non-myocardial arterial thromboembolic events
Cerebral hemorrhage neonatal	Non-myocardial arterial thromboembolic events
Cerebral hypoperfusion	Non-myocardial arterial thromboembolic events
Cerebral infarction	Non-myocardial arterial thromboembolic events
Cerebral infarction fetal	Non-myocardial arterial thromboembolic events
Cerebral ischemia	Non-myocardial arterial thromboembolic events

Cerebral septic infarct	Non-myocardial arterial thromboembolic events
Cerebral revascularization	Non-myocardial arterial thromboembolic events
Cerebral microhemorrhage	Non-myocardial arterial thromboembolic events
Cerebral small vessel ischemic disease	Non-myocardial arterial thromboembolic events
Cerebral thrombosis	Non-myocardial arterial thromboembolic events
Cerebral vasoconstriction	Non-myocardial arterial thromboembolic events
Cerebral venous thrombosis	Non-myocardial arterial thromboembolic events
Cerebrovascular accident	Non-myocardial arterial thromboembolic events
Cerebrovascular disorder	Non-myocardial arterial thromboembolic events
Cerebrovascular insufficiency	Non-myocardial arterial thromboembolic events
Cerebrovascular stenosis	Non-myocardial arterial thromboembolic events
Coeliac artery occlusion	Non-myocardial arterial thromboembolic events
Embolia cutis medicamentosa	Non-myocardial arterial thromboembolic events
Embolic cerebral infarction	Non-myocardial arterial thromboembolic events
Embolic stroke	Non-myocardial arterial thromboembolic events
Embolism	Non-myocardial arterial thromboembolic events
Embolism arterial	Non-myocardial arterial thromboembolic events
Endarterectomy	Non-myocardial arterial thromboembolic events
Femoral artery occlusion	Non-myocardial arterial thromboembolic events
Femoral artery embolism	Non-myocardial arterial thromboembolic events
Extradural hematoma	Non-myocardial arterial thromboembolic events
Epidural hemorrhage	Non-myocardial arterial thromboembolic events
Hemorrhage intracranial	Non-myocardial arterial thromboembolic events
Hemorrhagic cerebral infarction	Non-myocardial arterial thromboembolic events
Hemorrhagic stroke	Non-myocardial arterial thromboembolic events
Hemorrhagic transformation stroke	Non-myocardial arterial thromboembolic events
Hepatic artery thrombosis	Non-myocardial arterial thromboembolic events
Hepatic artery occlusion	Non-myocardial arterial thromboembolic events
Hepatic artery embolism	Non-myocardial arterial thromboembolic events
Hypthenar hammer syndrome	Non-myocardial arterial thromboembolic events
Hypoxic-ischemic encephalopathy	Non-myocardial arterial thromboembolic events
Inner ear infarction	Non-myocardial arterial thromboembolic events
Iliac artery occlusion	Non-myocardial arterial thromboembolic events
Iliac artery embolism	Non-myocardial arterial thromboembolic events
Intra-aortic balloon placement	Non-myocardial arterial thromboembolic events
Intracerebral hematoma evacuation	Non-myocardial arterial thromboembolic events
Intracranial hematoma	Non-myocardial arterial thromboembolic events
Intracranial tumour hemorrhage	Non-myocardial arterial thromboembolic events
Intraoperative cerebral artery occlusion	Non-myocardial arterial thromboembolic events
Intraventricular hemorrhage	Non-myocardial arterial thromboembolic events
Intraventricular hemorrhage neonatal	Non-myocardial arterial thromboembolic events
Ischemic cerebral infarction	Non-myocardial arterial thromboembolic events
Lacunar stroke	Non-myocardial arterial thromboembolic events

Lacunar infarction	Non-myocardial arterial thromboembolic events
Ischemic stroke	Non-myocardial arterial thromboembolic events
Lateral medullary syndrome	Non-myocardial arterial thromboembolic events
Left atrial appendage occlusion	Non-myocardial arterial thromboembolic events
Leriche syndrome	Non-myocardial arterial thromboembolic events
Meningorrhagia	Non-myocardial arterial thromboembolic events
Mesenteric artery stenosis	Non-myocardial arterial thromboembolic events
Mesenteric artery embolism	Non-myocardial arterial thromboembolic events
Mesenteric arteriosclerosis	Non-myocardial arterial thromboembolic events
Mesenteric arterial occlusion	Non-myocardial arterial thromboembolic events
Mesenteric artery stent insertion	Non-myocardial arterial thromboembolic events
Mesenteric artery thrombosis	Non-myocardial arterial thromboembolic events
Microembolism	Non-myocardial arterial thromboembolic events
Migrainous infarction	Non-myocardial arterial thromboembolic events
Millard-Gubler syndrome	Non-myocardial arterial thromboembolic events
Moyamoya disease	Non-myocardial arterial thromboembolic events
Penile artery occlusion	Non-myocardial arterial thromboembolic events
Percutaneous coronary intervention	Non-myocardial arterial thromboembolic events
Perinatal stroke	Non-myocardial arterial thromboembolic events
Peripheral arterial occlusive disease	Non-myocardial arterial thromboembolic events
Peripheral artery bypass	Non-myocardial arterial thromboembolic events
Peripheral artery angioplasty	Non-myocardial arterial thromboembolic events
Peripheral arterial reocclusion	Non-myocardial arterial thromboembolic events
Peripheral artery stent insertion	Non-myocardial arterial thromboembolic events
Peripheral artery thrombosis	Non-myocardial arterial thromboembolic events
Peripheral embolism	Non-myocardial arterial thromboembolic events
Peripheral endarterectomy	Non-myocardial arterial thromboembolic events
Periventricular hemorrhage neonatal	Non-myocardial arterial thromboembolic events
Pituitary hemorrhage	Non-myocardial arterial thromboembolic events
Popliteal artery entrapment syndrome	Non-myocardial arterial thromboembolic events
Post procedural stroke	Non-myocardial arterial thromboembolic events
Precerebral artery occlusion	Non-myocardial arterial thromboembolic events
Precerebral artery thrombosis	Non-myocardial arterial thromboembolic events
Pulmonary artery therapeutic procedure	Non-myocardial arterial thromboembolic events
Putamen hemorrhage	Non-myocardial arterial thromboembolic events
Pulmonary endarterectomy	Non-myocardial arterial thromboembolic events
Pulmonary artery thrombosis	Non-myocardial arterial thromboembolic events
Renal artery occlusion	Non-myocardial arterial thromboembolic events
Renal artery thrombosis	Non-myocardial arterial thromboembolic events
Renal embolism	Non-myocardial arterial thromboembolic events
Renal artery angioplasty	Non-myocardial arterial thromboembolic events
Reversible cerebral vasoconstriction syndrome	Non-myocardial arterial thromboembolic events

Reversible ischemic neurological deficit	Non-myocardial arterial thromboembolic events
Ruptured cerebral aneurysm	Non-myocardial arterial thromboembolic events
Spinal cord hemorrhage	Non-myocardial arterial thromboembolic events
Spinal cord hematoma	Non-myocardial arterial thromboembolic events
Spinal artery thrombosis	Non-myocardial arterial thromboembolic events
Spinal artery embolism	Non-myocardial arterial thromboembolic events
Spinal epidural hematoma	Non-myocardial arterial thromboembolic events
Spinal epidural hemorrhage	Non-myocardial arterial thromboembolic events
Spinal subarachnoid hemorrhage	Non-myocardial arterial thromboembolic events
Splenic artery thrombosis	Non-myocardial arterial thromboembolic events
Spinal subdural hemorrhage	Non-myocardial arterial thromboembolic events
Spinal subdural hematoma	Non-myocardial arterial thromboembolic events
Splenic embolism	Non-myocardial arterial thromboembolic events
Stress cardiomyopathy	Non-myocardial arterial thromboembolic events
Stroke in evolution	Non-myocardial arterial thromboembolic events
Subarachnoid hematoma	Non-myocardial arterial thromboembolic events
Subarachnoid hemorrhage	Non-myocardial arterial thromboembolic events
Subarachnoid hemorrhage neonatal	Non-myocardial arterial thromboembolic events
Subdural hematoma	Non-myocardial arterial thromboembolic events
Subclavian steal syndrome	Non-myocardial arterial thromboembolic events
Subclavian artery thrombosis	Non-myocardial arterial thromboembolic events
Subclavian artery occlusion	Non-myocardial arterial thromboembolic events
Subclavian artery embolism	Non-myocardial arterial thromboembolic events
Subdural hematoma evacuation	Non-myocardial arterial thromboembolic events
Subdural hemorrhage	Non-myocardial arterial thromboembolic events
Subdural hemorrhage neonatal	Non-myocardial arterial thromboembolic events
Superior mesenteric artery syndrome	Non-myocardial arterial thromboembolic events
Thalamic infarction	Non-myocardial arterial thromboembolic events
Thalamus hemorrhage	Non-myocardial arterial thromboembolic events
Thromboembolism	Non-myocardial arterial thromboembolic events
Thrombotic stroke	Non-myocardial arterial thromboembolic events
Thrombotic microangiopathy	Non-myocardial arterial thromboembolic events
Thrombotic cerebral infarction	Non-myocardial arterial thromboembolic events
Thrombotic thrombocytopenic purpura	Non-myocardial arterial thromboembolic events
Transient ischemic attack	Non-myocardial arterial thromboembolic events
Truncus coeliacus thrombosis	Non-myocardial arterial thromboembolic events
Vertebral artery occlusion	Non-myocardial arterial thromboembolic events
Vascular stent stenosis	Non-myocardial arterial thromboembolic events
Vascular stent restenosis	Non-myocardial arterial thromboembolic events
Vascular stent occlusion	Non-myocardial arterial thromboembolic events
Vascular encephalopathy	Non-myocardial arterial thromboembolic events
Vertebral artery perforation	Non-myocardial arterial thromboembolic events
Vertebral artery stenosis	Non-myocardial arterial thromboembolic events

Vertebral artery thrombosis	Non-myocardial arterial thromboembolic events
Vertebrobasilar insufficiency	Non-myocardial arterial thromboembolic events
Visual acuity reduced transiently	Non-myocardial arterial thromboembolic events
Axillary vein thrombosis	Venous thromboembolic events
Cerebral venous thrombosis	Venous thromboembolic events
Budd-Chiari syndrome	Venous thromboembolic events
Catheterisation venous	Venous thromboembolic events
Central venous catheterization	Venous thromboembolic events
Cavernous sinus thrombosis	Venous thromboembolic events
Compression stockings application	Venous thromboembolic events
Deep vein thrombosis	Venous thromboembolic events
Deep vein thrombosis postoperative	Venous thromboembolic events
Embolism	Venous thromboembolic events
Embolism venous	Venous thromboembolic events
Iliac vein occlusion	Venous thromboembolic events
Homans' sign positive	Venous thromboembolic events
Hepatic vein thrombosis	Venous thromboembolic events
Hepatic vein occlusion	Venous thromboembolic events
Inferior vena cava syndrome	Venous thromboembolic events
Inferior vena caval occlusion	Venous thromboembolic events
Intracranial venous sinus thrombosis	Venous thromboembolic events
Jugular vein thrombosis	Venous thromboembolic events
Mahler sign	Venous thromboembolic events
May-Thurner syndrome	Venous thromboembolic events
Mesenteric vein thrombosis	Venous thromboembolic events
Mesenteric venous occlusion	Venous thromboembolic events
Obstetrical pulmonary embolism	Venous thromboembolic events
Obstructive shock	Venous thromboembolic events
Ovarian vein thrombosis	Venous thromboembolic events
Penile vein thrombosis	Venous thromboembolic events
Pelvic venous thrombosis	Venous thromboembolic events
Paget-Schroetter syndrome	Venous thromboembolic events
Phlebectomy	Venous thromboembolic events
Portal vein cavernous transformation	Venous thromboembolic events
Portal vein occlusion	Venous thromboembolic events
Portal vein thrombosis	Venous thromboembolic events
Post procedural pulmonary embolism	Venous thromboembolic events
Post thrombotic syndrome	Venous thromboembolic events
Postoperative thrombosis	Venous thromboembolic events
Postpartum venous thrombosis	Venous thromboembolic events
Pulmonary embolism	Venous thromboembolic events
Pulmonary infarction	Venous thromboembolic events
Pulmonary microemboli	Venous thromboembolic events
Pulmonary thrombosis	Venous thromboembolic events

Pulmonary vein occlusion	Venous thromboembolic events
Pulmonary veno-occlusive disease	Venous thromboembolic events
Pulmonary venous thrombosis	Venous thromboembolic events
Renal vein thrombosis	Venous thromboembolic events
SI QIII TIII pattern	Venous thromboembolic events
Renal vein occlusion	Venous thromboembolic events
Renal vein embolism	Venous thromboembolic events
Splenic vein occlusion	Venous thromboembolic events
Splenic vein thrombosis	Venous thromboembolic events
Subclavian vein thrombosis	Venous thromboembolic events
Superior sagittal sinus thrombosis	Venous thromboembolic events
Thrombophlebitis	Venous thromboembolic events
Superior vena cava syndrome	Venous thromboembolic events
Superior vena cava occlusion	Venous thromboembolic events
Thrombophlebitis migrans	Venous thromboembolic events
Thrombophlebitis superficial	Venous thromboembolic events
Thrombosed varicose vein	Venous thromboembolic events
Thrombophlebitis neonatal	Venous thromboembolic events
Thrombosis corpora cavernosa	Venous thromboembolic events
Transverse sinus thrombosis	Venous thromboembolic events
Vascular graft	Venous thromboembolic events
Vena cava embolism	Venous thromboembolic events
Venogram abnormal	Venous thromboembolic events
Vena cava thrombosis	Venous thromboembolic events
Vena cava filter removal	Venous thromboembolic events
Vena cava filter insertion	Venous thromboembolic events
Venoocclusive disease	Venous thromboembolic events
Venoocclusive liver disease	Venous thromboembolic events
Venous occlusion	Venous thromboembolic events
Venous operation	Venous thromboembolic events
Venous recanalisation	Venous thromboembolic events
Venous repair	Venous thromboembolic events
Venous stent insertion	Venous thromboembolic events
Venous thrombosis	Venous thromboembolic events
Venous thrombosis in pregnancy	Venous thromboembolic events
Venous thrombosis limb	Venous thromboembolic events
Venous thrombosis neonatal	Venous thromboembolic events
Angle closure glaucoma	Glaucoma
Borderline glaucoma	Glaucoma
Developmental glaucoma	Glaucoma
Diabetic glaucoma	Glaucoma
Exfoliation glaucoma	Glaucoma
Fundoscopy abnormal	Glaucoma
Glaucoma	Glaucoma

Glaucoma drug therapy	Glaucoma
Glaucoma surgery	Glaucoma
Glaucoma traumatic	Glaucoma
Glaucomatocyclitic crises	Glaucoma
Glaucomatous optic disc atrophy	Glaucoma
Gonioscopy abnormal	Glaucoma
Halo vision	Glaucoma
Iridotomy	Glaucoma
Loss of visual contrast sensitivity	Glaucoma
Normal tension glaucoma	Glaucoma
Open angle glaucoma	Glaucoma
Ophthalmic fluid drainage	Glaucoma
Optic discs blurred	Glaucoma
Optic nerve cup/disc ratio increased	Glaucoma
Pigmentary glaucoma	Glaucoma
Phacotrabeculectomy	Glaucoma
Phacolytic glaucoma	Glaucoma
Optic nerve cupping	Glaucoma
Pupillary light reflex tests abnormal	Glaucoma
Slit-lamp tests abnormal	Glaucoma
Uveitic glaucoma	Glaucoma
Trabeculoplasty	Glaucoma
Trabeculectomy	Glaucoma
Uveitisglaucoma-hyphaema syndrome	Glaucoma
Visual fieldtests abnormal	Glaucoma
Accidental overdose	Overdose due to overfill of the pre-filled syringe
Chemical poisoning	Overdose due to overfill of the pre-filled syringe
Accidental poisoning	Overdose due to overfill of the pre-filled syringe
Intentional overdose	Overdose due to overfill of the pre-filled syringe
Exposure to toxic agent	Overdose due to overfill of the pre-filled syringe
Toxicity to various agents	Overdose due to overfill of the pre-filled syringe
Prescribed overdose	Overdose due to overfill of the pre-filled syringe
Poisoning deliberate	Overdose due to overfill of the pre-filled syringe
Overdose Poisoning	Overdose due to overfill of the pre-filled syringe
OR checkbox 'Overdose' ticked for PFS drug preparation only	Overdose due to overfill of the pre-filled syringe

MedDRA, Medical Dictionary for Drug Regulatory Activities; PFS, pre-filled syringe, RMP, Risk Management Plan