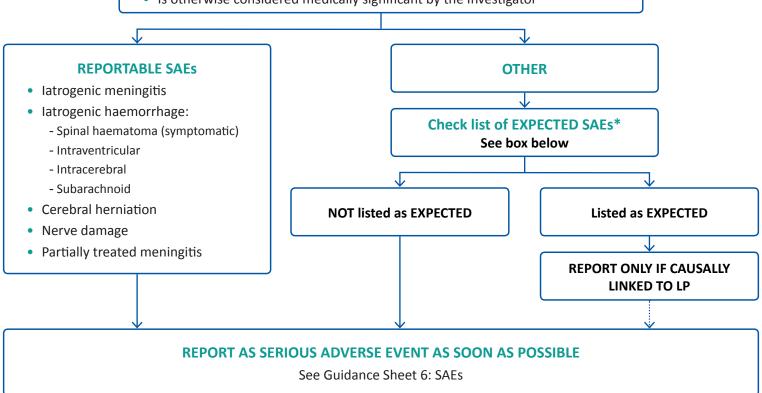
## **NeoCLEAR SAE Flowchart**



## **SERIOUS ADVERSE EVENT (SAE)**

## Any event which:

- · Results in death
- Is life-threatening
- Requires participant hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is an important medical event
- Is otherwise considered medically significant by the Investigator



## \*EXPECTED SAEs

- Anaemia
- Clinically significant intracranial abnormality on cranial ultrasound scan – intracranial haemorrhage or white matter injury
- Chronic lung disease/Broncho pulmonary dysplasia
- Coagulopathy requiring treatment
- Death
- · Establishment of enteral feeding
- Failed LP, or infection, resulting in prolonged hospitalisation
- Hyperbilirubinemia (jaundice)
- Hypoglycaemia
- Hypoxic ischaemic encephalopathy
- · Low sodium level/hyponatremia

- Non-iatrogenic meningitis
- · Necrotising enterocolitis
- Patent ductus arteriosus
- Pneumothorax or air leaks
- Pneumonia
- Pulmonary haemorrhage
- Pulmonary hypertension
- Respiratory failure
- Retinopathy of prematurity
- Seizures
- Sepsis/infection
- Thrombocytopenia
- Hypotension