

Sponsor Ref:	
Study Title:	
Chief Investigator:	
Principal Investigator:	
Study Centre:	

Serious Adverse Event Listing Table

Patient Study ID	Date of SAE <i>dd/mm/yyyy</i>	Date Study Team Aware <i>(dd/mm/yy)</i>	Title of Event	Serious Criteria <i>(1-6)*</i>	Assessment of relationship to procedure/intervention/IMP <i>(Related/Unrelated)</i>	Outcome <i>(1-5)‡</i>	Date Initial Report sent to Sponsor <i>dd/mm/yyyy</i>	Date Follow up/final report sent to Sponsor <i>dd/mm/yyyy</i>	Date Sponsor confirmed SAE closed <i>dd/mm/yyyy</i>

*1 – Resulted in death, 2 – Life threatening, 3 – Inpatient hospitalisation or prolongation of existing hospitalisation, 4- Persistent or significant disability/incapacity, 5 - Congenital anomaly/birth defect, 6- Other.

‡1 - Resolved, 2 - Resolved with sequelae, 3- On-going, 4- Unknown, 5 – Fatal.