

Subject ID			

Initials		



## AE Log

DESCRIPTION OF ADVERSE EVENT	ONSET DATE	DATE REPORTED TO INVESTIGATOR	SEVERITY	RELATIONSHIP TO TRIAL DRUG	IS THIS A SAE?	IS THIS A REPORTABLE SAE	SIGNATURE AND DATE	ACTION TAKEN please list all that apply	OUTCOME	DATE RESOLVED
Where possible give diagnosis. If diagnosis is not known give sign or symptom. Update if diagnosis is determined.	DD/MM/YYYY	DD/MM/YYYY	1. Mild 2. Moderate 3. Severe	1. None 2. Possible 3. Probable 4. Definite		If YES, complete an SAE form	PI or delegated doctor	1. None 2. Hospitalisation 3. IMP temp stopped 4. IMP permanently stopped 5. Con Meds commenced (record on Con Meds Log) 6. Other (specify)	1. Recovered 2. Recovered with sequelae 3. Recovering 4. Not recovered 5. Unknown 6. Fatal	Enter date resolved / date of death / tick if ongoing (* see below)
1	___/___/___	___/___/___			Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	___/___/___			___/___/___ or <input type="checkbox"/>
2	___/___/___	___/___/___			Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	___/___/___			___/___/___ or <input type="checkbox"/>
3	___/___/___	___/___/___			Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	___/___/___			___/___/___ or <input type="checkbox"/>
4	___/___/___	___/___/___			Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	___/___/___			___/___/___ or <input type="checkbox"/>
5	___/___/___	___/___/___			Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	___/___/___			___/___/___ or <input type="checkbox"/>
6	___/___/___	___/___/___			Y <input type="checkbox"/> N <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>	___/___/___			___/___/___ or <input type="checkbox"/>

\*AEs & SAEs must be followed up until resolved or 30 days after last trial visit. If still ongoing at last trial visit contact participant 30 days after last trial visit and update AE log if required. SUSARs must be followed up until resolved.