

Participant ID				

Initials		



## AE Log

DESCRIPTION OF ADVERSE EVENT	ONSET DATE	DATE REPORTED TO INVESTIGATOR	SEVERITY	RELATIONSHIP TO TRIAL DRUG	IS THIS AN SAE?	ACTION TAKEN please list all that apply	OUTCOME	DATE RESOLVED	SIGNATURE AND DATE
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, report to the online Tayside Pharmacovigilance System.	1. None 2. Hospitalisation 3. Intervention stopped 4. ConMeds commenced (record on ConMeds Log) 5. Other (specify)	1. Recovered 2. Recovered with sequelae 3. Recovering 4. Not recovered 5. Unknown 6. Fatal	Enter date resolved / date of death / date of last contact/ tick if ongoing (* see below)	PI or delegated doctor
1	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>			__/__/__ or <input type="checkbox"/>	__/__/__
2	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>			__/__/__ or <input type="checkbox"/>	__/__/__
3	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>			__/__/__ or <input type="checkbox"/>	__/__/__
4	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>			__/__/__ or <input type="checkbox"/>	__/__/__
5	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>			__/__/__ or <input type="checkbox"/>	__/__/__
6	__/__/__	__/__/__			Y <input type="checkbox"/> N <input type="checkbox"/>			__/__/__ or <input type="checkbox"/>	__/__/__

**SAEs** need to be reported to Tayside Pharmacovigilance System within 24h of becoming aware of SAE. **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.

\*if the outcome of the AE is 1.Recovered, 2.Recovered with sequelae or 6.Fatal enter Date resolved or Date of death or enter date of last contact once participant has left the trial.