

Participant ID			

Initials		



ADVERSE EVENT TERM	ONSET DATE	DATE REPORTED TO INVESTIGATOR	SEVERITY	RELATIONSHIP TO TRIAL DRUG	IS THIS A SAE?	SIGNATURE	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. Unrelated 2. Possible 3. Probable 4. Definite	If yes has an SAE form been completed? Y ☐ N ☐ Report within 10 days: http://hicservices.dundee.ac.uk/pharmacovigilance/	PI or delegated doctor Date must be within 7 days of AE reported to Investigator otherwise it is a breach	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 recovered/ date of death /date of last contact (* see below)
1	__/__/__	__/__/__			Y ☐ N ☐	Y ☐ N ☐			__/__/__
2	__/__/__	__/__/__			Y ☐ N ☐	Y ☐ N ☐			__/__/__
3	__/__/__	__/__/__			Y ☐ N ☐	Y ☐ N ☐			__/__/__
4	__/__/__	__/__/__			Y ☐ N ☐	Y ☐ N ☐			__/__/__
5	__/__/__	__/__/__			Y ☐ N ☐	Y ☐ N ☐			__/__/__
6	__/__/__	__/__/__			Y ☐ N ☐	Y ☐ N ☐			__/__/__

AEs & SAEs must be followed up until resolved or until 30 days after participant's last visit. **SUSARs** must be followed up until resolved.

*If the outcome of the AE is '1.Recovered', '2.Recovered with sequelae' or '6.Fatal' then enter 'Date resolved' or 'Date of death'.

*If the Outcome is '3.Recovering', '4.Not Recovered' or '5.Unknown' then enter the 'Date of last contact'.

