

Participant ID [_][_][_][_]

Initials [_][_][_]



GREAT-2 Worksheet

Adverse Event Log

DID THIS ADVERSE EVENT OCCUR DURING ADMINISTRATION OF TRIAL MEDICATION?	DESCRIPTION OF ADVERSE EVENT	ONSET DATE	DATE REPORTED TO INVESTIGATOR	SEVERITY	RELATIONSHIP TO TRIAL DRUG	IS THIS AN SAE? If Yes, complete SAE form	ACTION TAKEN please list all that apply	OUTCOME	DATE RESOLVED	SIGNATURE AND DATE
Y/N	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	Y/N	1. None 2. Hospitalisation 3. Intervention stopped 4. Con Meds commenced (record on Con Meds 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. Tick if ongoing (*see below)	PI or delegated doctor must sign & date
									.../.../... or <input type="checkbox"/>	
									.../.../... or <input type="checkbox"/>	
									.../.../... or <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.

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