**Adverse Events**

Subject Initials Subject Number

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| Event No | Adverse Event Description  (use a diagnosis rather than symptoms where possible to facilitate event coding at the end of trial) | Start date  DD-MMM-YYYY | End date  DD-MMM-YYYY | Or indicate here if ongoing at study end | Intensity (1) | Relation to study drug (2) | Action taken (3) | Outcome (4) | Serious? Y/N (if Y complete SAE log and report to Sponsor if applicable) | Entered by (initials as per delegation log) |
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1: 1-mild; 2-moderate; 3-severe

2: 1-Reasonable possibility of causal relationship to a study drug; 2-Unrelated or unlikely to be related to a study drug

3: 1-none; 2-study drug dose reduced; 3-study drug withdrawn; 4-specific treatment (record on concomitant medication page); 5-other

4: 1-recovered; 2-recovering; 3-not recovered; 4-recovered with sequelae; 5-fatal; 6-unknown