

ADVERSE EVENTS* FORM	Participant UTIN
	___/___/___

*Refer to SOP no. 4 (AE and Serious AE Reporting) for further actions required if participant experiences an AE.

Adverse event (AE)		Date reported	DD / MMM / YYYY
AE timeframe	AE onset date	AE end date	DD / MMM / YYYY
Intensity	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	Serious AE	<input type="checkbox"/> Serious <input type="checkbox"/> Non serious
Is the AE likely to be due to the intervention?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the AE expected? <i>Expected reactions will be found in SmPC (http://emc.medicines.org.uk/) and/or protocol.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Outcome of AE	<input type="checkbox"/> Resolved <input type="checkbox"/> Improved <input type="checkbox"/> Fatal (<i>if yes, specify date of death</i> DD / MMM / YYYY)	<input type="checkbox"/> Resolved with sequelae (<i>If yes, specify</i>) <input type="checkbox"/> Persisting	<input type="checkbox"/> Worsened <input type="checkbox"/> Unknown