ISRCTN71327395
HTA 09/22/136

Adverse Events

ADVERSE EVENTS	Area No	Site No	Participant I.D.	Participant initials

Please record details of all new adverse events, AEs which have increased severity, changes in relationship to study treatment and all medical conditions present at study treatment initiation which have worsened. ***If the subject has not experienced any adverse events please enter "NONE".***

	1	2
Adverse Event		
Onset Date	Day Month Year	Day Month Year
Onset Time	Hours : Minutes	Hours : Minutes
Stop Date	Day Month Year	Day Month Year
Duration	Value Time Period **1** = Days **2** = Hours **3** = Minutes **4** = Seconds	Value Time Period **1** = Days **2** = Hours **3** = Minutes **4** = Seconds
Severity	**1** = Mild **2** = Moderate **3** = Severe	**1** = Mild **2** = Moderate **3** = Severe
Relationship to study treatment	**0** = Not Related **1** = Possibly Related **2** = Definitely Related	**0** = Not Related **1** = Possibly Related **2** = Definitely Related
Action taken	**0** = No action taken **1** = Treatment Adjusted **2** = Treatment Discontinued **3** = Concomitant Medication **4** = Non-drug therapy given **5** = Hospitalisation	**0** = No action taken **1** = Treatment Adjusted **2** = Treatment Discontinued **3** = Concomitant Medication **4** = Non-drug therapy given **5** = Hospitalisation
Outcome	**1** = Resolved **2** = Ongoing at Follow-Up	**1** = Resolved **2** = Ongoing at Follow-Up
Serious?	**0** = No **1** = Yes	**0** = No **1** = Yes

Completed by:

Name: Signature:	Day Month Year	Adverse Events Version 1.0 270411

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	3	4
Adverse Event		
Onset Date	Day Month Year	Day Month Year
Onset Time	Hours : Minutes	Hours : Minutes
Stop Date	Day Month Year	Day Month Year
Duration	Value Time Period **1** = Days **2** = Hours **3** = Minutes **4** = Seconds	Value Time Period **1** = Days **2** = Hours **3** = Minutes **4** = Seconds
Severity	**1** = Mild **2** = Moderate **3** = Severe	**1** = Mild **2** = Moderate **3** = Severe
Relationship to study treatment	**0** = Not Related **1** = Possibly Related **2** = Definitely Related	**0** = Not Related **1** = Possibly Related **2** = Definitely Related
Action taken	**0** = No action taken **1** = Treatment Adjusted **2** = Treatment Discontinued **3** = Concomitant Medication **4** = Non-drug therapy given **5** = Hospitalisation	**0** = No action taken **1** = Treatment Adjusted **2** = Treatment Discontinued **3** = Concomitant Medication **4** = Non-drug therapy given **5** = Hospitalisation
Outcome	**1** = Resolved **2** = Ongoing at Follow-Up	**1** = Resolved **2** = Ongoing at Follow-Up
Serious?	**0** = No **1** = Yes	**0** = No **1** = Yes

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Adverse Events

Adverse Event Reporting Key

1. Severity :

   Mild: Transient or mild discomfort, no limitation in activity, no medical intervention/therapy required,

   Moderate: Mild to moderate limitation in activity, some assistance in activity, some assistance may be needed, no or minimal medical intervention required,

   Severe: Marked limitation in activity, some assistance usually required, medical intervention required, hospitalisation possible
2. Relationship (to any study intervention): 0= Not Related, 1=Possibly Related, 2 = Definitely Related
3. Action taken: if yes record the therapy on current medication page of the case report form.
4. Serious : If yes please complete a SAE Report form and fax to Newcastle Clinical Trials Unit within 24 hours of being aware of event.

   Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

   - **Results in death**
   - **Is life-threatening** – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
   - **Requires re-admission to hospital-, or prolongation of existing inpatient's hospitalisation**
   - **Results in persistent or significant disability or incapacity**

     Is a congenital anomaly or birth defect