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Serious Adverse Event (SAE) Report

Area No Site No Participant I.	D. Participant initials					
<u>URGENT</u> - FAX FORM TO NCTU, NEWCASTLE-UPON-TYNE ON 0191 222 8901						
1. REPORT TYPE: INITIAL FOLLOW-UP						
SUBJECT DETAILS: (please see notes on page	3 on ethnicity codes for this form)					
(200) (200)	DATE OF Day Month Year IRTH					
SERIOUS ADVERSE EVENT (SAE) DETAILS	S:					
6. SAE IN MEDICAL TERMS (DIAGNOSIS IF POSSIBLE): 7. CASE DESCRIPTION OF ABOVE SAE: (include related signs/ symptoms, suspected cause, record any						
information on changes or modifications to the intervention – please continue on separate page if required)						
8. ONSET OF FIRST SIGN/SYMPTOM OF SAE: O	NSET TIME (IF KNOWN) 9. SEVERITY:					
Day Month Year	Hour Minutes					
10. SERIOUSNESS: Subject died AND/OR Day Month Year See key below and insert all appropriate number(s) for SAE (may be more than one)	11. OUTCOME OF SAE: Completely Recovered (enter date of recovery below): Day Month Year See key below and insert appropriate number.					
1 = Life-threatening 2 = Involved or Prolonged inpatient hospitalisation 3 = Involved persistent or significant disability or incapacity 4 - Other significant medical event 5 = Recovered with sequelae 6 = Condition improving 7 = Condition still present & unchanged 8 = Condition deteriorated 9 = Death (if yes, provide autopsy report if autopsy performed)						
12. RELEVANT MEDICAL HISTORY: (including allerg	gy, drug or alcohol abuse, family history)					



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STUDY INTERV	STUDY INTERVENTION DETAILS:								
13. STUDY INTERVENTION DATES: DATE OF IUT:				14. OTHER INVESTIGATIONS/TREATMENT (SPECIFY:					
Day Month Year DATE OF SURGERY FOR SUI: Day Month Year									l
						Day	Month	Year	
15. ACTION TAKEN. Please mark all as appropriate: No Action taken Drug therapy given									
			L						
Other (non-drug) treatment given Treatment (e.g. drug, cisc etc) permanently discontinued due to this adverse event Hospitalisation Treatment (e.g.drug, cisc) temporarily interrupted or reduced									
Please provide full details of any treatment given for the SAE below (e.g. drugs / non-drug treatment, details of treatment reduction / interruption / discontinuation):									
16. RELEVANT (_					1
Brand name/generic name	Indication	Daily Dose (eg 75mg)	Route (eg po)			Start date	End date	Ongoing (y/n)	
17. RELEVANT TEST/LAB FINDINGS: (enter only those findings necessary for SAE diagnosis or course description)									
Test or Lab Name	Date	Date			Results (value + units if applicable)				

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verified Date Initials	c o m p u t e r	is e d	c h e c	k e d
m o n i t o r e d Date Initials	Date	Initials	Date	Initials



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18. ASSESSMENT OF CAUSALITY (requires medical decision). In your medical judgement, is there a							
reasonable possibility that the event may have been caused by the trial intervention? YES OR NO NO NOTE - If causality is "YES" for trial intervention, please also indicate whether the nature or severity of SAE is "expected" or "unexpected" for the trial intervention (see Appendix 2 of trial protocol for further details)							
Expected OR Unexpected Day Month Year Medical signature							
<u>Medical</u> signa		INFORMATIO	NI SOLID				
19. Name, profession, address and telephone number of reporter			20. Reporting date (by person reporting event) Day Month Year				
Reporter signature							
		NCTU INFO	RMATIO	N			
Date NCTU notifie	d of SAE		SAE ID	Code (dictated by NC	TU)		

Notes on coding ethnicity -

Please write in the box the code number from the list below that applies to the subject.

- 1. Caucasian
- 2. Black
- 3. Asian
- 4. Other

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