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Academic and Clinical Central Office for Research and Development

NHS Lothian

SERIOUS ADVERSE EVENT (SAE) FORM (CTIMP)

DO NOT SEND PATIENT IDENTIFIABLE DATA OR SOURCE DOCUMENTS WITH THIS FORM*

Study name:		**Participant ID:**	
EudraCT number:		**Date of report (dd/mm/yyyy):**	

TO BE COMPLETED BY ACCORD (*INTERNAL USE ONLY*)	
Date of Receipt:	
Information Complete: ☐ Yes ☐ No *Initials:*	Follow-up Requested: ☐ Yes ☐ No Details:

1. REPORT DETAILS

Centre ID:	**Centre name:**	**Country SAE reported from:**
Report stage: **Initial** ☐ **Submitted** (dd/mm/yyyy)**:**		**Date PI first notified of SAE** (dd/mm/yyyy)**:**
Report stage: **Follow-up** ☐ **Submitted** (dd/mm/yyyy)**:**		

2. EVENT DETAILS

Date of onset (dd/mm/yyyy)**:**	**Diagnosis:**

Description of SAE in medical terms:

Seriousness Criteria (check all that are relevant to the event)**:**

☐ Participant died
☐ Inpatient hospitalisation or prolongation of existing inpatient hospitalisation
☐ Life-threatening
☐ Involved persistent or significant disability or incapacity
☐ Congenital anomaly/ birth defect
☐ Other significant medical event

Other SAE criteria:

☐ Recommendation of the DMC
☐ New events/reactions likely to affect the safety of participants
☐ Post study SUSAR

Severity of event: ☐ Mild ☐ Moderate ☐ Severe

Is the event due to progression of underlying disease? ☐Yes ☐No
Is the event due to a lack of efficacy of IMP? ☐Yes ☐No
If yes, please indicate which IMP(s):

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3. STUDY TREATMENT

IMP(s) (if blinded, suspected IMP)	Dose /schedule	Route of administration	Start date (dd/mm/yyyy)	End date (dd/mm/yyyy) or tick box if ongoing	Causally Related to IMP? *Tick either unrelated or possibly related*		Expected (Y/N)
					Unrelated	Possibly Related	
1.				☐			
2.				☐			
3.				☐			

4. NIMPs (Non-investigational medicinal products)

Are there any additional medications **used as part of the protocol** (e.g. rescue medications or escape medications for the study IMP)? *Such medications are referred to as NIMPs*

Yes ☐ No ☐

If yes, please complete the table below

NIMP(s)	Dose/ schedule	Route of administration	Start date (dd/mm/yyyy)	End date (dd/mm/yyyy) or tick box if ongoing	Causally Related to NIMP? *Tick either unrelated or possibly related*		Expected (Y/N/NA)
					Unrelated	Possibly Related	
1.				☐			
2.				☐			
3.				☐			

5. CONCOMITANT DRUGS RELEVANT TO THE SAE

☐Tick box if no relevant concomitant medication

Drug name	Dose/schedule	Route of administration	Reason for use	Start date (dd/mm/yyyy)	End date (dd/mm/yyyy)	Continued? (Y/N)
1.						
2.						
3.						
4.						

6. MEDICAL HISTORY *(list relevant medical history)*

☐Tick box if no relevant medical history

Condition	Start Date (dd/mm/yyyy)	End date (dd/mm/yyyy)	Ongoing (Y/N)	Medication required Y/N
1.				
2.				
3.				
4.				

7. RELEVANT TEST/LABORATORY FINDINGS *(include only the results relevant to the SAE diagnosis or course of SAE)*

☐Tick box if no relevant tests

Test/lab finding	Unit	Date (dd/mm/yyyy)	Value	Date (dd/mm/yyyy)	Value	Date (dd/mm/yyyy)
1.						

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2.						
3.						
4.						

Comment on test/laboratory findings (if none, mark as NA)

8. ACTION TAKEN *(section may be updated for follow up reports)*

☐ IMP permanently discontinued: *If multiple IMPs used, please record which IMP(s) have been discontinued:* Date discontinued (dd/mm/yyyy): *Initial and date (dd/mm/yyyy):*	☐ IMP dose reduced *If multiple IMPs used, please record which IMP(s) have been reduced:* Date reduced (dd/mm/yyyy): *Initial and date (dd/mm/yyyy):*	☐ IMP dose increased *If multiple IMPs used, please record which IMP(s) have been increased:* Date increased (dd/mm/yyyy): *Initial and date (dd/mm/yyyy):*
☐ IMP dose not changed *Initial and date (dd/mm/yyyy):*	☐ Unknown *Initial and date (dd/mm/yyyy):*	☐ Not applicable *Initial and date (dd/mm/yyyy):*

9. OUTCOME OF SAE *(section may be updated for follow up reports)*

☐ Completely recovered: Date recovered (dd/mm/yyyy): *Initial and date (dd/mm/yyyy):*	☐ Condition still present and unchanged *Initial and date (dd/mm/yyyy):*	☐ Recovered with sequelae: Date recovered (dd/mm/yyyy): *Initial and date (dd/mm/yyyy):*
☐ Condition deteriorated *Initial and date (dd/mm/yyyy):*	☐ Condition improving *Initial and date of initial (dd/mm/yyyy):*	☐ Death: Date of death (dd/mm/yyyy): Post mortem? Yes ☐ No ☐ *Initial and date (dd/mm/yyyy):*

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10. ADDITIONAL INFORMATION

11. INFORMATION SOURCE FOR INITIAL REPORT			
Name, address, telephone number and email address of person completing report:			
PI name:			
PI signature:		Date: dd/mm/yy	
ALL REPORTS MUST BE SIGNED AND DATED BY THE PRINICPAL INVESTIGATOR. PLEASE SCAN TO .pdf AND E-MAIL REPORTS TO ACCORD ([redacted]) ALTERNATIVELY, PLEASE FAX REPORTS TO ACCORD ON [redacted]			

12. INFORMATION SOURCE FOR FINAL FOLLOW UP REPORT			
Name, address, telephone number and email address of person completing report:			
PI name:			
PI signature:		Date: dd/mm/yy	
ALL REPORTS MUST BE SIGNED AND DATED BY THE PRINICPAL INVESTIGATOR. PLEASE SCAN TO .pdf AND E-MAIL REPORTS TO ACCORD ([redacted]) ALTERNATIVELY, PLEASE FAX REPORTS TO ACCORD ON [redacted]			