CONFIDENTIAL WHEN COMPLETED

SUNRRISE Trial

Serious Adverse Event (SAE) Form

Birmingham Clinical Trials Unit

To be completed for any serious adverse events occurring within the protocol-defined reporting period

1. Site Details			
Site Name:		Name of PI:	
2. Participant Details			
Trial Number:	☐☐☐☐☐	Participant Initials:	☐☐☐
3. Report type (use BCTU allocated unique SAE number if this is a follow-up or final report)			
Initial Report	☐	Follow-up Report	☐ → If a follow-up report, please insert the unique SAE number provided by BCTU following receipt of the initial report ☐☐☐
4. Event Information			
Signs and Symptoms			
5. Event Diagnosis			
Diagnosis			
6. Investigations and Treatment			
Investigation, results/ findings and interventions/ treatment	*(Where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only).*		

7. Seriousness of Event

Seriousness of event (please provide a response to each question)	No	Yes	Details	
Death	☐	☐	Date of death:	☐☐/☐☐☐/☐☐☐☐
			Cause of death:	
Life threatening event	☐	☐		
In-patient hospitalisation or prolongation of existing hospitalisation *If yes, tick the box to indicate if "prolonged" or "further admission"*	☐	☐	Prolonged	☐
			Initial (further admission after discharge):	☐ If ticked, date of admission: ☐☐/☐☐☐/☐☐☐☐
			Date of discharge:	☐☐/☐☐☐/☐☐☐☐
Persistent or significant disability/incapacity	☐	☐		
Other medical reason for reporting?	☐	☐	Please specify below:	

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8. Details of Event			
Date of onset	☐☐/☐☐☐/☐☐☐☐	Date became serious	☐☐/☐☐☐/☐☐☐☐
Date site became aware	☐☐/☐☐☐/☐☐☐☐	Date resolved **or** tick if ongoing ☐	☐☐/☐☐☐/☐☐☐☐

9. Causality Assessment		
Causal relationship of the event to the study Please select **one** category:	Unrelated ☐ Unlikely to be related ☐ Possibly related ☐	Probably related ☐ Definitely related ☐
If the event is unrelated, please provide details of an alternative explanation for the event		
List any underlying comorbidities, concomitant medications or investigations etc. that may be relevant.	*(Where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only).*	

10. Details of person reporting			
Name of person reporting	Job title of person reporting		Date reported
			☐☐/☐☐☐/☐☐☐☐
Signature of person reporting (must appear on delegation log)		Date of signature	☐☐/☐☐☐/☐☐☐☐
Signature of Principal Investigator		Date of PI signature	☐☐/☐☐☐/☐☐☐☐

Please ***report within 24 hours*** any SERIOUS ADVERSE EVENTS by completing the pages 1 and 2 of this form and faxing or emailing them to the SUNRRISE Trial Office: **0121 415 8871** or **SUNRRISE@trials.bham.ac.uk**

Once you have sent the form, and the event is resolved, please then send originals (with copies of any relevant reports) to **The SUNRRISE Trial Office, University of Birmingham Clinical Trials Unit, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT**

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Trial Number:		Participant Initials:		Unique SAE number:	

TO BE COMPLETED BY THE CHIEF INVESTIGATOR OR NAMED DELEGATE

Section 11-13 may be completed via an email from the Chief Investigator or named delegate.

11. Review of Causality by Chief Investigator or delegate	**12. Assessment of expectedness *with reference to the Protocol* by Chief Investigator or delegate**	
Review of Causality, please select **one** category: Unrelated ☐ Probably related ☐ Unlikely to be related ☐ Definitely related ☐ Possibly related ☐	This section should **only** be completed if causal relationship is classified as **possibly, probably or definitely related** in either section 8 and/or section 11.	Expected ☐ Unexpected ☐
Is the event related and unexpected? *Serious related and unexpected events require reporting to the REC and sponsor*	No ☐ Yes ☐	

13. Signatures - In signing this form the Investigator or delegate confirms the **Causality** and **Expectedness** of the event

This section may initially be completed via an email from the Chief Investigator or delegate

Name of Chief Investigator or delegate	Signature of CI or delegate	Date of CI or delegate signature
		☐☐/☐☐☐/☐☐☐☐

14. Classification of event

System Organ Classification (SOC) - please indicate the event classification below: ***(please tick all that apply)***

☐ Infections & infestations	☐ Ear & labyrinth disorders	☐ Vascular disorders
☐ Eye disorders	☐ Nervous system disorders	☐ Congenital, familial & genetic disorders
☐ Blood & lymphatic system disorders	☐ Skin & subcutaneous tissue disorders	☐ Social circumstances
☐ Immune system disorders	☐ Renal & urinary disorders	☐ Investigations
☐ Endocrine disorders	☐ Gastrointestinal disorders	☐ Surgical & medical procedures
☐ Metabolism and nutrition disorders	☐ Hepatobiliary disorders	☐ Cardiac disorders
☐ Psychiatric disorders	☐ Reproductive system & breast disorders	☐ Injury, poisoning & procedural complications
☐ Respiratory, thoracic & mediastinal disorders	☐ Pregnancy, puerperium & perinatal conditions	☐ General disorders & administration site conditions
☐ Neoplasms benign, malignant & unspecified (incl. cysts & polyps)	☐ Musculoskeletal & connective tissue disorders	☐ Other, please specify: _____ _____

Clavian- Dindo - please indicate the classification below:

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ n/a

FOR OFFICE USE ONLY

SAE Reference Number	☐☐☐
Is this the Final Report for this SAE?	No ☐ Yes ☐
Date reported to REC	☐☐/☐☐☐/☐☐☐☐
Date reported to Sponsor	☐☐/☐☐☐/☐☐☐☐