Joint Arrangements for Research

Serious Adverse Event report - NNUH sponsored CTIMP studies

What are you reporting?	
SAE / SAR ☐	SUSAR* ☐
***Note: If you are reporting a SUSAR the randomisation code for that participant will have to be unblinded**	
Report Type:	Initial ☐ Follow-up Report ☐ Follow-up Report #
Study information	
Study Title: (short)	
Sponsor:	**Chief Investigator Name:** **Email Address:**
Eudract Number: *(for CTIMPs only)*	**R&D Reference Number / IRAS Number:**
Protocol title and version number:	
Version and date of approved Reference Safety Information (RSI) in use at onset of SAE:	
Site Number: *(for multi-site studies only)*	**Site Name:**
Principal Investigator	**Name:** **Email address:**
Date of site becoming aware of the event *(dd/mm/yy)*:	
Participant information	
Participant initials:	**Participant Gender:** ☐ Male ☐ Female
Participant Randomisation No:	

Evaluation of Event Please refer to definitions and Appendix 1 &2 in SOP 205 for guide on understanding of seriousness, relatedness, expectedness.	
Event/Reaction: *(keywords; e.g. body site, symptoms, severity, treatment)*	
Date of onset: *(dd/mm/yy)*	**Date person completing form became aware of event:** *(dd/mm/yy)*
Criteria for definition as SAE	☐ Congenital abnormality/birth defect ☐ Resulted in death ☐ Life threatening ☐ In patient hospitalisation/prolongation of hospitalisation ☐ Persistent or significant disability ☐ is otherwise considered medically significant by the investigator ** If there is more than one criterion, choose the more/most significant one.*
Describe event: *(A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re-challenge details if applicable. Please include the point in the study at which the event occurred.)*	
In the investigators opinion was the event related to a research procedure?	☐ Definitely ☐ Likely ☐ Possibly ☐ Unlikely ☐ Not related
Please specify which procedure if applicable	
In the investigators opinion was the event related to the Investigational Medicinal Product?	☐ Definitely ☐ Likely ☐ Possibly ☐ Unlikely ☐ Not related
Action taken with study drug/participant:	☐ None ☐ Dose temporarily reduced ☐ Dose reduced

	☐ Discontinued temporarily ☐ Discontinued ☐ Participant withdrawn from trial
If related to IMP was this reaction unexpected (Suspected Unexpected Serious Adverse Reaction – SUSAR)?	☐ Yes ☐ No ☐ Not applicable
Did event/reaction abate after stopping drug?	☐ Yes ☐ No ☐ Not applicable
Did event/reaction reappear after reintroduction of drug?	☐ Yes ☐ No ☐ Not applicable

IMP & concomitant medication information

Drug details (Daily dose and generic name)	Route of Administration (IV / Oral etc.)	Therapy Start Date (dd/mm/yy)	Therapy End Date (dd/mm/yy)	Date of last administered Dose prior to SAE onset (dd/mm/yy)	Indications for Use

Have urgent safety measures been implemented? ☐ Yes ☐ No ☐ Not applicable	**If yes, please detail below:**

Outcome of event

What is the outcome of the SAE?	**Date event resolved:** *(dd/mm/yy)*	**Date patient died:** *(dd/mm/yy)*

☐ Recovered ☐ Recovered with sequalae ☐ Continuing ☐ Resulted in death ☐ Unknown		
Cause of death obtained from:	☐ Coroner's inquest ☐ Death certificate ☐ Working diagnosis	

Contact and signatures
Please supply contact details where further information may be obtained: **Person to contact:** **Phone number:** **Email address:**

Signature ***(person completing report)*** **Print name** **Date**

PI Signature ***(if multicentre trial)*** **Print name** **Date**

CI Signature ***(if not completing report)*** **Print name** **Date**

Please send the completed form to rdsae@nnuh.nhs.uk .

For R&D Office use only

For SUSAR only:	Date reported to the REC: Date reported to MHRA:

For NNUH sponsored trial REVIEW BY NNUH MEDICAL ADVISOR	Medical Advisor comments:
SIGNED:	
Name (print):	
Date:	