Joint Arrangements for Research

Serious Adverse Event report – Non CTIMP

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:		
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 DOB: *(dd/mm/yy)*	**Participant initials:**	**Participant Gender:** ☐ Male ☐ Female
Participant Randomisation No:		

Evaluation of Event		
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 ** 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 / treatment / intervention?	☐ Definitely ☐ Likely ☐ Possibly ☐ Unlikely ☐ Not related	
Please specify which procedure / treatment / intervention (if applicable)		
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** *(dd/mm/yy)*

_____

PI Signature ***(if multicentre trial)*** **Print name** **Date** *(dd/mm/yy)*

_____

CI Signature ***(if not completing report)*** **Print name** **Date** *(dd/mm/yy)*

If the study is sponsored by NNUH please send the completed form to rdsae@nnuh.nhs.uk .

If the study is sponsored by the University of East Anglia and Hosted by NNUH, please scan and email the form to researchsponsor@uea.ac.uk and rdsae@nnuh.nhs.uk.

For R&D Office use only

Date form RECEIVED by R&D team: *(dd/mm/yy)* ( )	Reviewed by: Date reviewed: ( ) *(dd/mm/yy)*
For SUSAR only:	Date reported to the REC: (Date reported to MHRA: (