

Joint Arrangements for Research

Serious Adverse Event report - NNUH sponsored CTIMP studies

What are you reporting?	
SAE / SAR <input type="checkbox"/>	SUSAR* <input type="checkbox"/>
<i>*Note: If you are reporting a SUSAR the randomisation code for that participant will have to be unblinded</i>	
Report Type:	Initial <input type="checkbox"/> Follow-up Report <input type="checkbox"/> Follow-up Report #
Study information	
Study Title: (short)	
Sponsor:	Chief Investigator Name: Email Address:
Eudract Number: <i>(for CTIMPs only)</i>	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: <i>(for multi-site studies only)</i>	Site Name:
Principal Investigator	Name: Email address:
Date of site becoming aware of the event (dd/mm/yy):	
Participant information	
Participant initials:	Participant Gender: <input type="checkbox"/> Male <input type="checkbox"/> 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: <i>(keywords; e.g. body site, symptoms, severity, treatment)</i>	
Date of onset: <i>(dd/mm/yy)</i>	Date person completing form became aware of event: <i>(dd/mm/yy)</i>
Criteria for definition as SAE	<input type="checkbox"/> Congenital abnormality/birth defect <input type="checkbox"/> Resulted in death <input type="checkbox"/> Life threatening <input type="checkbox"/> In patient hospitalisation/prolongation of hospitalisation <input type="checkbox"/> Persistent or significant disability <input type="checkbox"/> is otherwise considered medically significant by the investigator <i>* If there is more than one criterion, choose the more/most significant one.</i>
Describe event: <i>(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.)</i>	
In the investigators opinion was the event related to a research procedure?	<input type="checkbox"/> Definitely <input type="checkbox"/> Likely <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Not related
Please specify which procedure if applicable	
In the investigators opinion was the event related to the Investigational Medicinal Product?	<input type="checkbox"/> Definitely <input type="checkbox"/> Likely <input type="checkbox"/> Possibly <input type="checkbox"/> Unlikely <input type="checkbox"/> Not related
Action taken with study drug/participant:	<input type="checkbox"/> None <input type="checkbox"/> Dose temporarily reduced <input type="checkbox"/> Dose reduced

		<input type="checkbox"/> Discontinued temporarily <input type="checkbox"/> Discontinued <input type="checkbox"/> Participant withdrawn from trial			
If related to IMP was this reaction unexpected (Suspected Unexpected Serious Adverse Reaction – SUSAR)?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable			
Did event/reaction abate after stopping drug?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable			
Did event/reaction reappear after reintroduction of drug?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable		If yes, please detail below:			
Outcome of event					
What is the outcome of the SAE?		Date event resolved: <i>(dd/mm/yy)</i>		Date patient died: <i>(dd/mm/yy)</i>	

<input type="checkbox"/> Recovered <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Continuing <input type="checkbox"/> Resulted in death <input type="checkbox"/> Unknown		
Cause of death obtained from:		<input type="checkbox"/> Coroner's inquest <input type="checkbox"/> Death certificate <input type="checkbox"/> Working diagnosis

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

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