University of East Anglia

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NHS Foundation Trust

Joint Arrangements for Research

Adverse Event report - Medical Device

What are you reporting?	
SAE / SADE ☐	USADE ☐*
If the event is related and unanticipated it is an Unexpected Serious Adverse Device Event (USADE) and requires expedited reporting. Inform the Sponsor immediately.	
Is the Study Device Blinded or Unblinded? Blinded ☐ Unblinded ☐ **Has the subject been unblinded?** Yes ☐ No ☐ N/A ☐ **Was the event related to a protocol violation?** Yes ☐ No ☐ **Was the subject withdrawn due to this event?** Yes ☐ No ☐	
Report Type:	Initial Report ☐ Follow-up Report ☐ Final Report ☐
Study information	
Study Title: (short)	
Sponsor:	**Chief Investigator Name:** **Email Address:**
EUDAMED - ID:	**R&D Reference Number / IRAS Number:**
Clinical Investigation Plan 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 ☐ other e.g. 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	

Study Medical Device Information: If more than one device is being used, please complete for each device

Subject has been fitted / used / treated with the device? Yes ☐ No ☐

If No - Give Reason (i.e. screening)

If Yes, provide details in the table below:

Name of Device	Indication for use	Route of administration / use	Date of first use	Date of last use

In the investigators opinion was the event related to the device?	☐ Definitely ☐ Likely ☐ Possibly ☐ Unlikely ☐ Not related
Action taken with Device	☐ None ☐ Device schedule adjusted ☐ Device Permanently Removed/Discontinued Date: ☐ Other – provide details Detail treatment given: ☐ Unknown at time of report ☐ Not applicable

If related to the device was this reaction unexpected (Unexpected Serious Adverse Device Event – USADE)?

☐ Yes…….☐ No ☐ Not applicable

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:**		

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Signature ***(person completing report)*** **Print name** **Date** *(dd/mm/yy)*

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

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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.