NCTU SAE Reference:

University Hospitals of Derby and Burton NHS Foundation Trust

Serious Adverse Event/Reaction Reporting Form

Please send a copy of the SAE form to the NCTU by email nctu-sae@nottingham.ac.uk or by fax on 0115 7484091.

All SAEs to be reported to the NCTU within one working day.

1: Study Information			
Study Title:	POSNOC – a randomised trial of armpit (axilla) treatment for women with early stage breast cancer	**DHFT Study Reference:**	**DHRD/2014/043**
Name of individual completing report:		**Date of report:**	DD/MMM/YYYY
Email address of person completing report			
Site name/ number:		**Principal Investigator:**	

2: Participant Information			
Subject ID:		**Date of Birth:**	DD/MMM/YYYY
Initials:		**Gender:**	☐ Male ☐ Female

3: Adverse Event Details			
Event Term *(diagnosis where possible)*:			
Description of event: (*Specify diagnosis or cause of death if known; otherwise provide signs and symptoms, relevant tests/results)*			
Date of onset:	DD/MMM/YYYY	**Severity:**	☐ Mild ☐ Moderate ☐ Severe
Date of site awareness:	DD/MMM/YYYY		

Serious criteria:	**Outcome:**	
☐ Death ☐ Life threatening ☐ Hospitalisation or prolongation of hospital stay ☐ Persistent or significant disability or incapacity ☐ Congenital abnormality or birth defect ☐ Other	☐ On-going ☐ Fatal ☐ Recovered/Resolved ☐ Recovered/Resolved with sequalae ☐ Unknown	
	Date of death / resolution *(if applicable)*:	DD/MMM/YYYY

NCTU SAE Reference:

University Hospitals of Derby and Burton NHS Foundation Trust

Participant status:		
☐ Continuing ☐ Completed ☐ Withdrawn	**Date of completion / withdrawal** *(if applicable)*:	DD/MMM/YYYY

Causality:	**Expectedness** (ONLY required if related)**:**
☐ Related ☐ Not Related	☐ Expected ☐ Unexpected
*****NOTE: Must be completed by PI or authorised designee*****	

Name & Signature of Person making decision:	Name	Signature

If the event is:

- **Related** – i.e. occurs as a result of a research procedure(s) **AND**
- **Unexpected** – i.e. the event(s) is not listed in the protocol as an expected occurrence

Then it is classed as a 'SUSAR' and must be reported within 15 days of becoming aware of the event to:

(1) the REC that approved the study

(2) the sponsor (dhft.randdsae@nhs.net)

4: Relevant Information			
Any relevant medical history?	☐ Yes ☐ No	**Details** *(continue on separate sheet if necessary)*:	
Any relevant concomitant medication?	☐ Yes ☐ No	**Details** *(Include dose, units, duration. Continue on separate sheet if necessary)*:	

5: PI sign off	
PI name:	
PI signature:	
Date:	DD/MMM/YYYY

6: CI sign off	
Agree with PI's assessment of event?	☐ Yes ☐ No *(If no please detail)*……
CI name:	
CI signature:	
Date:	DD/MMM/YYYY

7: NCTU sign off (if applicable)			
Date report received:	DD/MMM/YYYY	**Comments:**	

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Name of receiver:		**Signature of receiver:**	
Follow Up required:	☐ Yes ☐ No	**Event classification:**	☐ SAE ☐ SUSAR ☐ SAR
Date SUSAR reported to REC:	DD/MMM/YYYY	**Other CI's/PI's informed of SUSAR?**	☐ Yes ☐ No