SERIOUS ADVERSE EVENT REPORTING

NHS
National Institute for Health Research

Serious Adverse Event Reporting Form

(BOSS RELATED INCIDENTS ONLY)

BOSS TRIAL OFFICE
GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST

Any inpatient admission (or prolongations of existing admissions) that may be related to a trial procedure will constitute a Serious Adverse Event and should be reported on this Serious Adverse Event Reporting Form. For the purpose of this trial please report any oesophageal or endoscopy related SAEs.

Please complete the entire form with as much detail as is available at the time of admission, tick "initial report" and e mail it to the BOSS office within 24 hours of becoming aware of the admission. Also forward the form, to your Trust R&D Manager. Once the stay is complete, please collect the necessary clinical detail, complete the form again, tick "on Discharge / Death" and fax it to us within 24 hours, again forwarding it to your R&D Manager.

INITIAL REPORTING:
For all initial reporting of any Serious Adverse Events / Incidents this form must be completed **fully** (hard copy or fax) and sent to the BOSS Trial Office and the Trust R&D Manager for the site within 24 hours of the incident occurring or being known.

FOLLOW-UP INFORMATION:
For subsequent follow-up reporting of an SAE, a new SAE reporting form should be completed with just administration details and all new or missing information **only filled in** and forwarded to the BOSS Trial Office and the Trust R&D Manager for the site as soon as possible. All SAEs must be followed up until closure.

NOTES:
A days admission to hospital will be calculated from the admission and discharge dates, there will be no need to enter times of admission and discharge. An important measurement within health economics for BOSS is length of stay(s(in high cost areas such as CCU, HDU and / or ICU. Therefore when completing this form we would require the total number of days that each patient spent in those areas. So if they went to HDU on two separate occasions for a stay of 2 and 4 days respectively during their whole stay in hospital then we would require 6 days to be noted on the form.

The ICD 10 code identifies the International Classification of Disease, which can be obtained from your hospital coders, however this information does not need to be obtained at the time of completion and submission but can be forwarded at a later date. We will chase missing codes once a year or at site visit(s). The ICD 10 code will be used by the Health Economists to calculate the costs of a stay in hospital.

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Please complete details of any SAE from the time of informed consent. For guidance on which events to report please refer to the study protocol

Please fax this form to the BOSS Trial Office on 03004 225486

STUDY DETAILS	
Study Title	**BOSS (Barrett's Oesophagus Surveillance Study)**
R&D Project ID No.	

PATIENT / TREATMENT DETAILS			
Patient Initials		Patient Study Number	
Date of Birth (d d m m y y y y)		Weight	kg
Gender	☐ Male ☐ Female		
Patient Hospital Number			
Responsible Clinician:		Institution:	
Randomisation Details	☐ Surveillance ☐ Endoscopy at Need		

Type of report ☐ Initial ☐ on Discharge / Death	Was the Chief or Principal Investigator informed of this event prior to the completion of this form? ☐ Yes ☐ No

REASON FOR ADMISSION – please explain

	Outcome
	☐ Resolved ☐ Persisting ☐ Worsened ☐ Fatal ☐ Not assessable

Admission date (d d m m y y) | Discharge date (d d m m y y) | Number of days in admission to : ☐ CCU ☐ HDU ☐ ICU | ICD 10 Code

WHY WAS THIS ADMISSION RELATED TO A BOSS PROCEDURE – please explain

	Event Type
	☐ Resulted in death, **please record date of death below* ☐ Life -threatening ☐ Prolonged existing hospitalisation ☐ Resulted in persistent or significant disability / incapacity ☐ Other *(specify)* _____

Data of most recent Endoscopy before Event (d d m m y y y y)

Date of death (d d m m y y y y)

Serious Adverse Event Term *(enter the Main Event in the first row followed by any associated symptoms. There should be one MAIN Event per form. If there are two events, please complete two forms)*	**Date of Onset** (d d m m y y)	**SAE Status** 1 – resolved 2 – Resolved with sequelae 3 – ongoing 4 – worsened 5 - Fatal	**Date resolved** (d d m m y y)
		☐	
Associated symptoms:			
		☐	
		☐	

INVESTIGATOR ASSESSMENT OF RELATEDNESS TO ENDOSCOPY *[to be completed only when all information is to hand]*				
Not related ☐	Unlikely to be related ☐	Possible related ☐	Probably related ☐	Very likely related ☐
Data of most recent Endoscopy before Event ☐☐☐☐☐☐☐☐ d d m m y y y y				

ACTION TAKEN			
*Treatment delayed ☐	*Treatment delayed and reduced ☐	Treatment permanently stopped ☐	Name of person making decision

Treatment given for management of SAE

Treatment	Total daily dose	Route 1 = oral 2 = intravenous 3 = subcutaneous 4 = other	Start date	Ongoing?	End date
			☐☐☐☐☐☐ d d m m y y	☐ Y ☐ N	☐☐☐☐☐☐ d d m m y y
			☐☐☐☐☐☐ d d m m y y	☐ Y ☐ N	☐☐☐☐☐☐ d d m m y y

Any concomitant medications? ☐ Y ☐ N ***(If yes, please specify below and continue on separate sheet if necessary)***

Treatment	Total daily dose	Route 1 = oral 2 = intravenous 3 = subcutaneous 4 = other	Start date	Ongoing?	End date
			☐☐☐☐☐☐ d d m m y y	☐ Y ☐ N	☐☐☐☐☐☐ d d m m y y
			☐☐☐☐☐☐ d d m m y y	☐ Y ☐ N	☐☐☐☐☐☐ d d m m y y

Any relevant tests / laboratory data? ☐ Y ☐ N ***(If yes, please specify below /continue on separate sheet if necessary or attach print outs)***

Any other relevant information? ☐ Y ☐ N ***(If yes, please specify below and continue on separate sheet if necessary)***

Principle investigator assessment of expectedness	Expected ☐	Unexpected ☐	*Is the event listed in the reference document, (study protocol)?*

Event summary description *(Give a concise medical description of the event including all relevant symptoms. Please specify the grade for all related symptoms and complete page overleaf for all that meet the definition of serious)*

Signature *[Authorised health professional]*	Print name	Date of report ☐☐☐☐☐☐ d d m m y y

Number of pages of supplementary reports to follow: ☐

OFFICE USE ONLY

Date SAE reported to R&D Unit ☐☐☐☐☐☐ d d m m y y	Date SAE reviewed ☐☐☐☐☐☐ d d m m y y
Date reported to Main REC ☐☐☐☐☐☐ d d m m y y	Reported to all other PIs ☐ Y ☐ N

Form checked by (signature)	Print name	Date ☐☐☐☐☐☐ d d m m y y

Comments: