Adverse Events template

UH Bristol Investigator's Template for recording Adverse Events **v3.4**

(Page 1 of 1)

Full title of Study			
Ethics No:		UH Bristol Project Registration no:	

Sheet number : ___ of

AE No:	Patient ID	Description of Event	Start date	Duration/End date	Outcome	**Sequelae
					☐ Resolved ☐ Ongoing ☐ Ongoing with sequelae**	

Assessment			
Intensity:	☐ mild ☐ moderate ☐ severe	Expectedness	☐ expected ☐ unexpected i.e. not described in protocol, product information or investigator brochure.
Causality: Relationship to study drug/device/intervention	☐ not related ☐ unlikely to be related ☐ possibly related ☐ probably related ☐ definitely related	Seriousness	☐ Not serious ☐ Results in death* ☐ Life threatening* ☐ Results in hospitalisation or prolongation of existing hospitalisation* ☐ Results in disability or incapacity* ☐ Congenital anomaly or birth defect* ☐ Other (please specify)*

* Event is considered serious – report to the sponsor and UH Bristol R&I Department within 24 hours using the form provided. Where none is provided use the UH Bristol Research Related SAE/SUSAR Initial Report Form

SAE initial report form

R&I use only: case reference number		Date report received by R&I	

RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM

1. Person making report	
Name:	
Job title/role in study:	
Contact address:	
Email address:	
Telephone No:	
Fax number:	

2. Details of study	
Full Title of Study:	Study site (e.g. Hospital name):
	UH Bristol R&I Project Registration No:
	Ethics No: EudraCT No (IMP studies only):

3. Details of subject affected by SAE/SUSAR					
Subject study ID	Initials	DoB	Gender	Weight	Height

4. Details of SAE/SUSAR (further space available in section 12)

Full description of event/reaction, including body site, reported signs and symptoms and diagnosis where possible:

Event is defined as serious because it (tick as many as apply):	*Specify:
☐ resulted in death ☐ is/was life-threatening ☐ resulted in persistent or significant disability/incapacity ☐ required hospitalisation ☐ prolonged an ongoing hospitalisation ☐ resulted in a congenital anomaly or birth defect ☐ other – please specify* **Please give further details in section 6 'Outcome'**	

Maximum intensity (up until time of initial report)	Mild ☐	Moderate ☐	Severe ☐

Onset Date (when event became serious)	**Onset Time**	**End date**	**End time**	***OR* Duration**

Signature of person making report: _____Date:____/____/____

R&I use only: case reference number	

To be completed by the per son filling in the SAE form					
UH Bristol R&I number:		*Subject ID/initials*		*Onset date of SAE*	

RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM

Sheet number: _____of _____

5. Details of IMP/device/intervention(s) if applicable (further space available in section 12)

Brand name:	Indication	Batch no.	Route (e.g. oral)	Form (e.g. tablet)	Total dose/24h (specify unit s)	Regimen (e.g. BD)	Start date & time	Stop date & time	Suspected cause of SAE /SUSAR? (Y/N)

For blinded studies, was the randomisation code broken?		*Yes		No
*If yes, give details:				

Continue on new sheet if necessary; please identify how many sheets have been used.

Signature of person making report:_____Date:____/____/____

R&I use only: case reference number	

To be completed by the person filling in the SAE form					
UH Bristol R&I no.:		*Subject ID/initials*		*Onset date of SAE*	

RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM

6. Outcome (further space available in section 12)		
☐ Resolved*	☐ Ongoing*	☐ Died* (give cause and PM details if available)
*Give details:		
Was the patient withdrawn from the study?	Yes ☐	No ☐

7. Location of (onset of) SAE (further space available in section 12)
Setting (e.g. hospital*, home, GP, nursing home):
*If SAE occurred on UH Bristol precinct give exact location:

8. Action taken and further information (further space available in section 12)
Please describe action taken (including details of IMP where applicable e.g. drug withdrawn etc…):
Other information relevant to assessment of case e.g. medical history, family history, test results.

9. Causality and Expectedness (to be completed by physician)		
Is the SAE related to the drug/device/intervention? ☐ Not related ☐ Unlikely to be related ☐ Possibly related* ☐ Probably related* ☐ Definitely related*	*If possibly, probably or definitely related, was the SAE unexpected? ☐ Yes[1] ☐ No[2] (Unexpected means not described in the protocol or other product information)	***In addition to this form, and within 5 days:*** **1 - Please complete and return all sections of the follow up report form.** **2 - Please complete and return sections 1, 2 and 3 of the follow up report form.**

10. Sponsor notification (only complete where sponsor is not UH Bristol)	
Has the Sponsor been notified of the SAE/SUSAR?	☐ Yes, give date: ☐ No[+]
[+]***Please note, you must inform the Sponsor within 24 hours of becoming aware of the event.***	

(a) **Signature of person making report: _____Date:____/____/____**

R&I use only: case reference number	

To be completed by the person filling in the SAE form					
UH Bristol R&I no.:		*Subject ID/initials*		*Onset date of SAE*	

(b) **RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM** (Page 4 of 4)

11. Additional information (refer to section number)	
Section no.	Further information

12. Chief/Principal Investigator, or delegated physician (at this site)	
Name:	
Job title/role in study:	
Contact address:	
Email address:	
Telephone No:	
Fax number:	
Signature:	
I confirm that the contents of this form (pages 1, 2, 3 ± 4) are accurate and complete	

Please tick this box if additional pages have been used: ☐

(c) **Signature of person making report: _____Date:____/____/____**

R&I use only: case reference number		Date Received	

To be completed by the person filling in the SAE form					
UH Bristol R&I no.:		*Subject ID/initials*		*Onset date of SAE*	