Appendix B – SAE initial report form

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

OSAC TRIAL - SAE/SUSAR INITIAL REPORT FORM

Please complete for any SAE/SUSAR affecting any OSAC trial participants which:

- Results in death
- Is life threatening
- Results in persistent or significant disability / incapacity
- Requires hospitalisation
- Prolongs a current hospitalisation
- Results in a congenital abnormality or birth defect
- Other: an adverse event the nature or severity of which is not consistent with the known information about the drug provided in the Summary of Medicinal Product Characteristics (which is also summarised in the trial protocol and in the Full Patient Information Booklet)

1. Person making report (please complete all asterisked fields)	
Name: *	
Job title/role in study: *	
Contact address: *	
Email address: *	
Telephone No: *	
Fax number: *	

2. Details of study	
Full Title of Study: OSAC (Oral Steroids for Acute Cough) Trial Chief Investigator: Dr Alastair Hay ISRCTN #: MHRA ref #: 03299/0015/001-0001	Study site, e.g. GP practice name:* UH Bristol R&I Project Registration No: UoB1581 Ethics No: 12/SW/0180 EudraCT No. (IMP studies only): 2012_000851-15

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:*

Appendix B – SAE initial report form

<table>
<tr><td colspan="3">Event is defined as serious because it (tick as many as apply) *:
☐ 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 (see right)
Please give further details in section 6 ‘Outcome’</td><td colspan="2">If ‘Other’, please specify:</td></tr>
<tr><td colspan="2">Maximum intensity (up until time of initial report)*</td><td>Mild ☐</td><td>Moderate ☐</td><td>Severe ☐</td></tr>
<tr><td>Onset Date* (when event became serious):</td><td>Onset Time:*</td><td>End date:*</td><td>End time:*</td><td>OR Duration:*</td></tr>
</table>

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

Appendix B – SAE initial report form

R&I use only: case reference number	

To be completed by the person filling in the SAE form:					
UH Bristol R&I number:	UoB 1581	Subject ID/initials:*		Onset date of SAE: *	

Sheet number: _____of _____

5. Details of IMP (further space available in section 11)									
Brand name	**Indication**	**Patient ID***	**Route (e.g. oral)**	**Form (e.g. tablet)**	**Total dose/24h (specify units)**	**Regimen (e.g. b.d)**	**Start date & time***	**Stop date & time***	**Suspected cause of SAE /SUSAR? (Y/N) ***
Prednisolone	acute cough (OSAC trial entry)		oral	tablet	2 x 20mg	Daily x 5 days (sooner if symptoms resolve)			
For blinded studies, was the randomisation code broken? *				Yes (see below)* ☐		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: ____/____/____

Appendix B – SAE initial report form

R&I use only: case reference number	

To be completed by the person filling in the SAE form:					
UH Bristol R&I number:	UoB 1581	Subject ID/initials:*		Onset date of SAE: *	

6. Outcome (further space available in section 11)		
☐ Resolved*	☐ Ongoing*	☐ Died* (give cause and PM details if available)
Please give details:*		
Was the patient withdrawn from the study?	Yes ☐	No ☐

7. Location of (onset of) SAE (further space available in section 11)
Setting (e.g. hospital, home, GP, nursing home – name/address):

8. Action taken and further information (further space available in section 11)
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 OSAC Chief Investigator or Deputy)		
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 working 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.	

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

Appendix B – SAE initial report form

R&I use only: case reference number	

To be completed by the person filling in the SAE form:					
UH Bristol R&I number:	UoB 1581	Subject ID/initials:*		Onset date of SAE: *	

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

12. OSAC Trial Chief Investigator or Deputy	
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 ± 5) are accurate and complete	

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

Signature of person making report: _____ **Date:____/____/____**

FOR ALL REPORTING STAFF: Please fax this form directly to UH Bristol Monitor within 24 hours of becoming aware of event. Fax: 0117 324 0239.

FOR GP SITES ONLY: Please fax a copy of the form to the Bristol trial centre at same time as sending report to UH Bristol Monitor, file original in your trial site file and email Bristol to confirm receipt of fax. Fax: 0117 928 7341 / email: osac-trial@bristol.ac.uk

FOR BRISTOL TRIAL CENTRE: Please fax this form directly to UH Bristol Monitor as soon as possible after CI has completed and signed sections 9 and 12. File original/copy in the Trial Master File.