

# SAE/SAR Reporting Form

## Cover Sheet for Information Only

Study logo can be added here.

Blue text is instructional in this template and should be followed and removed before the document is finalised.

**Investigator Sites** please fax or email a copy of this form to the Chief Investigator **within 24 hours of notification of the event**

Trial Identifier (i.e.:COUGAR 02, Persephone)

**Chief Investigator:** Complete name

**Trial Co-ordinator/ Data Manager/ Research Nurse:**Delete as appropriate and complete name.

**Fax No:** This should be the detail of the person who will be processing the information

**Tel No:** This should be the detail of the person who will be processing the information

**Email:** This should be the detail of the person who will be processing the information

**Address:** This should be the detail of the person who will be processing the information, or a study specific address

### Definitions

**AE: Adverse Event.** Any untoward medical occurrence that happens to a patient or research participant to whom investigational medicinal Product has been administered in a clinical trial, which may or may not necessarily have causal relationship with the research being undertaken.

**SAE: Serious Adverse Event.** Any AE or effect that at any dose: Results in death; Is life threatening; Requires hospitalisation or prolongation of existing hospitalisation; Results in persistent or significant disability/incapacity; Is a congenital anomaly/birth defect; Is an otherwise significant event.

**AR: Adverse reaction.** An untoward and unintended reaction that is considered to be related to the administration of the IMP.

**SAR: Serious Adverse Reaction.** An SAE that is considered to be possibly, probably or definitely related to the IMP.

**SUSAR: Suspected Unexpected Serious Adverse Reaction.** An **adverse reaction**, which is both serious and unexpected, i.e. the nature or severity of which is not consistent with the applicable product information and which fulfils one or more of the criteria listed above for SAE.

**Initial Reporting:** For all initial reporting of any SAE/SARs this form must be **completed fully or with as much information as possible** and sent to the Cambridge Clinical Trials Unit or Chief Investigator if sending from a participating site within **24 hours** of the incident occurring or being reported to the trial team.

**Follow-up Information:** For subsequent follow-up reporting of an SAE/SAR, **a new SAE/SAR Reporting form should be completed with just the administration details and all new or missing information only** filled in and forwarded to the Cambridge Clinical Trials Unit or Chief Investigator if sending from a participating site as soon as possible. All SAE/Rs must be followed up until resolution.

**Expedited Reporting of SUSARs:** For any SUSARs which are life threatening/fatal, initial reports must be sent to the MHRA, the Main Research Ethics Committee (REC) and Sponsor by the Chief Investigator within 7 days of being aware of the event. Follow-up information must be sent to the MHRA, Main REC and Sponsor within 8 days of the initial report. All other SUSARs must be reported within 15 days and any follow-up information must be sent to the MHRA, Main REC and Sponsor as soon as possible. Participating sites must send these reports to the Chief Investigator.

**The Chief Investigator is expected to forward all SAE/R and SUSAR Reports and Follow-up information to the Cambridge Clinical Trials Unit if they are receiving documents from a participating site.**

**Cambridge Clinical Trials Unit    Email: [CCTU@addenbrookes.nhs.uk](mailto:CCTU@addenbrookes.nhs.uk)    Fax: 01223 256623**

Please fax or email a copy of this form to the Cambridge Clinical Trials Unit **within 24 hours of notification of the event**

**Return of Cover Page NOT required with completed form**

**Please ensure you are using the current version of this document. Please notify any changes required to the relevant QA Manager**

This document is reviewed and updated in line with emerging evidence or local requirements at least every two years

CCTU/FRM001

Rev.No 4.0

Approved: 07/03/2012

Cover Page



# SAE/SAR Reporting Form

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

Please fax or scan and email this form to {.....insert details here.....} within 24 hours of notification.

## Trial details Add electronically if desired

Study Title:

R&D No:

EudraCT No:

## Participant details

Initials:

Subject ID No:

Date of Birth:   /    /

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## Treatment details

IMP(s) patient was receiving at time of SAE (if applicable)	Dose	Units <i>i.e.: mg</i>	Freq. <i>i.e.: O/D</i>	Route of Admin. <i>Use codes</i>	Date of first dose	Action taken <i>Use codes</i>	Date of last treatment given prior to SAE	Causality <i>Use codes</i>	Expected/Unexpected <i>Use codes</i>	Name of Person making decision
<i>i.e.: Docetaxel</i>					<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> d d m m m y y		<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> d d m m m y y			
					<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> d d m m m y y		<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> d d m m m y y			
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<b>Codes:</b>	Route of Admin :	Action taken:	Causality:	Expectedness:
	1 = Oral 2 = IV 3 = Sub. Cut. 4 = Topical 5 = Suppository 6 = Other (please specify)	1 = None 2 = Dose Reduced 3 = Treatment Delayed 4 = Dose reduced & Delayed 5 = Drug stopped permanently 6 = Unknown	1 = Definitely 2 = Probably 3 = Possibly 4 = Unlikely 5 = Not related 6 = Unknown/ Not assessable	1 = Expected 2 = Unexpected

Most recent cycle no. (if applicable):

Was treatment given at full dose prior to event? Yes  No\*

\*Please specify:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Did reaction reappear after reintroduction of study medication? Yes  N/A  No

Did reaction abate after study medication stopped? Yes  N/A  No

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Please fax or scan and email this form to {.....insert details here.....} within 24 hours of notification.

## Trial details [Add electronically if desired](#)

Study Title:

R&D No:

EudraCT No:

## Participant details

Initials:

Subject ID No:

Date of Birth:   /    /

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## Concomitant medications & Treatment given to manage SAE

Con meds (if applicable)	Dose	Units <i>i.e.: mg</i>	Freq. <i>i.e.: O/D</i>	Route of Admin. <i>Use codes</i>	Date of first dose	Action taken <i>Use codes</i>	End date (if applicable)	Causality <i>Use codes</i>	Name of Person making decision
<i>i.e.:</i> Prednisolone					<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>		
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### Codes:

#### Causality:

- 1 = Definitely
- 2 = Probably
- 3 = Possibly
- 4 = Unlikely
- 5 = Not related
- 6 = Unknown/ Not assessable

#### Action taken:

- 1 = None
- 2 = Dose Reduced
- 3 = Treatment Delayed
- 4 = Dose reduced & Delayed
- 5 = Drug stopped permanently
- 6 = Unknown

#### Route of Admin :

- 1 = Oral
- 2 = IV
- 3 = Sub. Cut.
- 4 = Topical
- 5 = Suppository
- 6 = Other (please specify)

Treatment given to manage SAE (if applicable)	Dose	Units <i>i.e.: mg</i>	Freq. <i>i.e.: O/D</i>	Route of Admin. <i>Use codes</i>	Date of first dose	End date (if applicable)
<i>i.e.:</i> Paracetamol					<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
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## Any relevant medical history/ concurrent conditions?

Yes  No  (If yes, please specify below and continue on a separate sheet if necessary)

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Study Title:

R&D No:

EudraCT No:

## Participant details

Initials:    Subject ID No:

Date of Birth:   /    /      
d d m m m y y y y

## Any relevant tests/ laboratory data?

Yes  No  (If yes, please specify below and continue on a separate sheet if necessary or attached **anonymised** print outs)

Date	Investigation	Result	Date	Investigation	Result
<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <small>d d m m m y y</small>			<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <small>d d m m m y y</small>		
<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <small>d d m m m y y</small>			<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <small>d d m m m y y</small>		

Additional pages attached to this form:

Co-ordinating Site Trial SAE Ref. No:

## Principle Investigator Sign Off:

Was the event considered to be a SUSAR?  Yes  No

PI Signature:

PI Name Printed:

Date:   /    /    
d d m m m y y

## Chief Investigator Sign Off:

Agree with Principle Investigator assessment of event?  Yes *If no, please attach discussion with site & send the outcome in as Follow Up form*  
 No

CI Signature:

CI Name Printed:

Date:   /    /    
d d m m m y y

## Co-ordinating office use only:

Date event received in Co-ordinating office?   /    /    
d d m m m y y

Date SUSAR reported to Main REC:   /    /    
d d m m m y y

Co-ordinator Signature:

Has the event been reported as a SUSAR by co-ordinating site?  Yes  No

Date SUSAR reported to MHRA:   /    /    
d d m m m y y

Co-ordinator Name Printed:

N/A

Reported to other PIs?  Yes  No

Date:   /    /    
d d m m m y y

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