

# Other Important Safety Issue Reporting Form

## 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 Clinical Trials Unit **within 24 hours of notification of the event**

Study logo should 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 Title (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

### When to use:

Use to report any events that come to light that the Investigator considers significant but that do not fit into previously defined categories. These issues are subject to expedited reporting to the Sponsor. Examples include but are not limited to:

- Single case reports of an **expected** Serious Adverse Reaction which has an **unexpected outcome** (i.e. a fatal outcome).
- An increase in the rate of occurrence of an expected Serious Adverse Reaction, which is judged to be clinically important.
- Post Study SUSARs that occur after a participant has completed a clinical trial.
- A new event relating to the conduct or the development of a clinical trial:
- A serious adverse event relating to trial procedures and which could modify the conduct of the trial.
- Lack of efficacy of an IMP used for the treatment of life threatening disease.
- A major safety finding from a newly completed animal study

**Initial Reporting:** For all initial reporting of Other Important Safety issues this form must be **completed fully or with as much information as possible** and sent to the Clinical Trials Office (or Chief Investigator if sending from a remote site) within **24 hours** of the incident occurring or being known.

**Follow-up Information:** For subsequent follow-up reporting of an issue, **a new Reporting form should be completed with just the administration details and all new or missing information only** filled in and forwarded to the Clinical Trials Office (or the Chief Investigator if sending from a remote site) as soon as possible. All issues should be followed up until resolution.

**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/FRM004

Rev.No 3.0

Approved: 15/02/2012

Cover page

# Other Important Safety Issue Reporting Form

Please complete details of any Other Important Safety Issues 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 the Clinical Trials Unit or the Chief Investigator of the study within 24 hours of notification.**

Trial details <a href="#">Add electronically if desired</a>		Trial Subject details			
Study Title:	<input type="text"/>	Subject ID No:	<input type="text"/> <input type="text"/> <input type="text"/>	Trial No:	<input type="text"/>
R&D No:	<input type="text"/>	Date of Birth:	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	Trial SAE Ref. No:	<input type="text"/>
EudraCT No:	<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"/>		<small>d d m m m y y</small>		

Form is being used to report...	Description of Issue:
<input type="checkbox"/> A safety issue, which might materially alter the current risk-benefit assessment of an IMP	(Give concurrent conditions, medical history and consider drug/drug interactions) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<input type="checkbox"/> A safety issue that is sufficient to consider changes in the IMP administration	
<input type="checkbox"/> A safety issue that is sufficient to consider changes in the overall conduct of the trial	
<input type="checkbox"/> A safety issue, which was identified by a spontaneous report or a publication	
<input type="checkbox"/> Other, please specify in Description of the Issue	
	Cont. on separate sheet if necessary...

PI/CI:		
Date reported to Sponsor:	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	Was the event considered to be a <b>SUSAR?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No
	<small>d d m m m y y</small>	Additional pages attached to this form: <input type="checkbox"/> <input type="checkbox"/>
PI/CI Signature:	<input type="text"/>	PI/CI Name Printed: <input type="text"/>
		Date: <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>

Co-ordinating office use only:		
Was the event reported as a <b>SUSAR?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Date reported to Main REC: <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>
		Date reported to MHRA: <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>
Co-ordinator Signature:	<input type="text"/>	Co-ordinator Name Printed: <input type="text"/>
		Date: <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>

**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