

Pregnancy Reporting Form

Cambridge Clinical Trials Unit

Email: 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 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 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:

Used to report details of any pregnancy from the time of informed consent experienced by trial participant or by partner of trial participant.

Consent:

The mother must give her consent in order for the pregnancy to be followed up.

Initial Reporting: For all initial reporting of Pregnancy this form must be **completed fully or with as much information as possible** and send 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 a pregnancy, **a new Pregnancy 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 Pregnancies 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/FRM003

Rev.No 3.0

Approved: 15/02/2012

Cover Page

Pregnancy Reporting Form

Please complete details of any pregnancies 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 [Add electronically if desired](#)

Study Title:

R&D No:

EudraCT No: --

Trial Subject details

Subject ID No:

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

Trial No:

Trial SAE Ref. No:

Further Trial Subject details (Details of female partners of trial participants should be entered in Other Pregnancy Information section)

Gender: Male Female Centre:

Was the Study Drug unblinded? Yes N/A No

Type of Report: Initial Report
 Follow Up Report

Treatment details

IMP(s) patient was receiving at time of SAE (if applicable)	Dose	Units	Freq.	Route of Admin.	Date of first dose	Action taken	End date (if applicable)	Name of Person making decision
i.e.: Docetaxel		i.e.: mg	i.e.: O/D	Use codes	<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>	Use codes	<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>		<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>	

Codes:

Route of Admin :	Action taken:
1 = Oral	1 = None
2 = IV	2 = Dose Reduced
3 = Sub. Cut.	3 = Treatment Delayed
4 = Topical	4 = Drug stopped permanently
5 = Suppository	5 = Unknown
6 = Other	6 = N/A

Date of last treatment given prior to pregnancy: //
d d m m m y y

Was treatment given at full dose prior to event? Yes No*
 *Please specify:

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Trial details [Add electronically if desired](#)

Study Title:

R&D No:

EudraCT No: --

Trial Subject details

Subject ID No:

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

Trial No:

Trial SAE Ref. No:

Concomitant Treatment

IMP(s) patient was receiving at time of SAE (if applicable)	Dose	Units	Freq.	Route of Admin.	Date of first dose	Action taken	End date (if applicable)	Name of Person making decision
i.e.: Docetaxel		i.e.: mg	i.e.: O/D	Use codes	<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>	Use codes	<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>	
					<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>		<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>	

Codes:

Route of Admin :

- 1 = Oral
- 2 = IV
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- 4 = Topical
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- 6 = Other

Action taken:

- 1 = None
- 2 = Dose Reduced
- 3 = Treatment Delayed
- 4 = Drug stopped permanently
- 5 = Unknown
- 6 = N/A

PI/CI:

Date reported to Sponsor: //
d d m m m y y

Was the event considered to be a SUSAR? Yes No

Additional pages attached to this form:

PI/CI Signature:

PI/CI Name Printed:

Date: //
d d m m m y y

Co-ordinating office use only:

Was the event reported as a SUSAR? Yes No

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

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

Co-ordinator Signature:

Co-ordinator Name Printed:

Date: //
d d m m m y y

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