
SERIOUS ADVERSE EVENT REPORT

Please return to: Fax: Tel:

1. Clinical Trial Identification

| |
|-------------|
| Study Name: |
|-------------|

| | | |
|--|------------|---|
| Clinical Trial Identification e.g. EudraCT number | Project ID | Name of Principal Investigator Sponsor |
|--|------------|---|

2. Subject's Details

| Initials | Unique subject ID | Gender | Age and /or date of birth | Weight | Height |
|----------|-------------------|--------|---------------------------|--------|--------|
| | | | | | |

3. Date & Time of onset of SAE:

| | |
|-------------|------------|
| Date / / | Start time |
|-------------|------------|

4. Suspected investigational medicinal product(s):

| Trial therapy | Dosage form & strength | Daily dose and regimen (mg, ml, mg/kg) | Route of administration e.g. i.v. p.o. | Starting date | Date and time of last administration before SAE |
|---------------|------------------------|--|--|---------------|---|
| | | | | | |
| | | | | | |

5. Other treatment(s) - excluding those given to treat the SAE

| Name of therapy (medication, radiotherapy, others) | Dosage form & strength | Daily dose and regimen (mg,ml,mg/kg) | Route of administration e.g. i.v., p.o. | Starting date | Date and time of last administration before SAE |
|--|------------------------|--------------------------------------|---|---------------|---|
| | | | | | |
| | | | | | |

Please use additional sheet if necessary

6. Assessment

| | |
|-------------------------|---------------|
| Reason for seriousness: | December 2004 |
|-------------------------|---------------|

| | |
|---|---|
| <input type="checkbox"/> Fatal <input type="checkbox"/> Life-threatening <input type="checkbox"/> Required or prolonged hospitalisation (except elective surgery or progression of disease) <input type="checkbox"/> Resulted in severe or permanent disability <input type="checkbox"/> Unexpected grade 4 toxicity | <input type="checkbox"/> Overdose <input type="checkbox"/> Second primary cancer <input type="checkbox"/> Congenital anomaly <input type="checkbox"/> Other medically significant condition, specify: |
|---|---|

| | |
|--|--|
| Causality assessment regarding protocol treatment (by P.I or a delegated person - sub-investigator) | |
| <input type="checkbox"/> Unrelated <input type="checkbox"/> Unlikely / remote <input type="checkbox"/> Possible <input type="checkbox"/> Probable | <input type="checkbox"/> Definite <input type="checkbox"/> Cannot be classified, in the investigator's opinion, the event was most likely due to: |

7. Description of event

Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious should be given. In addition to a description of the reported signs and symptoms, whenever possible attempts should be made to establish a specific diagnosis for the reaction:

Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations:

Unblinding: yes no December 2004

8. Details of reporter of event/suspected ADR

| | |
|--|-------------------|
| Telephone number | |
| Email | |
| Name & signature of person completing form if completed by someone other than the P.I. or sub-investigator | Date: / / |
| Signature of P.I. (or sub-investigator) | Date: / / |

9. Administrative and Sponsor details – to be completed by R&D

| |
|----------------------|
| Date of this report: |
|----------------------|

| |
|--|
| Date event report was first received by sponsor: |
|--|

| |
|---|
| Case reference number (sponsor's/manufacture's identification number for the case) (this number must be the same for the initial and follow-up reports on the same case): |
|---|

| Sent to MHRA (date): | Sent to ethics committee (date): | Date of follow-up form |
|----------------------|----------------------------------|------------------------|
| | | |

SERIOUS ADVERSE EVENT - FOLLOW UP FORM

Please return to: Trial.report@uclh.c December 2004

: 020 7380 6978

1. Clinical Trial Identification

| |
|-------------|
| Study Name: |
|-------------|

| | | |
|---|-----------------|--------------------------------|
| Clinical Trial Identification e.g. EudraCT number or CTA | UCLH Project ID | Name of Principal Investigator |
|---|-----------------|--------------------------------|

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2. Date of onset of SAE:

| |
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3. Case reference number

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4. Outcome

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| <p>Outcome: information on recovery an any sequelae; what specific tests and /or treatments may have been required an their result; for a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction should be provided. Any autopsy or other post-mortem findings (including a coroner's report) should also be provided when available.</p> |
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5. Date resolved and time (if known)

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How do you currently classify caus:

December 2004

| | |
|--|---|
| Causality assessment regarding protocol treatment: | |
| <input type="radio"/> Unrelated <input type="radio"/> Unlikely / remote <input type="radio"/> Possible <input type="radio"/> Probable | <input type="radio"/> Definite <input type="radio"/> Cannot be classified, in the investigator's opinion, the event was most likely due to: |

6. In your opinion does the event now necessitate:

| |
|--|
| <input type="radio"/> A protocol amendment <input type="radio"/> Change to patient information sheet <input type="radio"/> Neither |
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