RD&E Sponsored & Hosted Studies

Serious Adverse Event / Serious Adverse Reaction / Suspected Unexpected Serious Adverse Reaction Report Form

Please complete, sign and scan to R&D at rde-tr.RandDSafetyReporting@nhs.net within 24 hours of knowledge of event.

### Section 1: Study Details

| Title of study: |  |
| R&D reference number: | Patient's study number: |
| CI or PI name: |  |
| Is this study a CTIMP? | No | Yes | If Yes, CI or PI is required to sign this form. |
| Is this study sponsored or hosted by the RD&E? | Sponsored | Hosted |

### Section 2: Summary

| Date of onset: | Date Investigator Team aware: |
| Report status: | First report to R&D | Follow-up report | Final Report |
| Type of report: | SAE* | SAR* | SUSAR** |

**Serious Adverse Event/Serious Adverse Reaction**

Any adverse event, adverse reaction or unexpected adverse reaction is defined as *serious* if it, at any dose (please tick):

- [ ] Results in death
- [ ] Is life-threatening
- [ ] Requires hospitalisation (minimum overnight stay), or prolongation of an existing hospitalisation
- [ ] Results in persistent or significant disability or incapacity
- [ ] Is a congenital anomaly or birth defect (i.e. mother involved in research)
- [ ] Other (as required by Sponsor)

**Suspected Unexpected Serious Adverse Reaction**

Any adverse reaction that is classed as serious and is suspected to be caused by the IMP its nature and severity are not consistent with the information about the medicinal product set out in:

(a) The summary of product characteristics (SPC) for that product (for a product with a marketing authorisation);
(b) The investigator's brochure relating to the trial in question (for a product without marketing authorisation).

**Summary of event/reaction:**

*You can attach the sponsor form if this covers all the information on this form, and insert just a one-line summary here to refer.*

Continue overleaf if needed
## Section 3: Evaluation

**NB:** This section must be evaluated and received by R&D within 5 working days

Tick box if awaiting PI review

<table>
<thead>
<tr>
<th>Severity</th>
<th>Minor</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Causality</td>
<td>Not related</td>
<td>Unlikely related</td>
<td>Possibly related</td>
</tr>
</tbody>
</table>

**NB:** If possibly, probably or definitely related, please assess the expectedness

<table>
<thead>
<tr>
<th>Expectedness</th>
<th>Expected (reaction previously identified and described in protocol and/or IB/SPC)</th>
<th>Unexpected (reaction not previously described in the protocol and/or IB/SPC)</th>
</tr>
</thead>
</table>

If the SAE/SAR is definitely related to the IMP and is unexpected, it is by definition a SUSAR and requires expedited reporting. Ensure R&D is informed immediately.

## Section 4: Actions & Outcomes

Outcome of event:

- [ ] Recovered
- [ ] Continuing*
- [ ] Death

*If continuing, please provide updates to R&D as soon as possible until resolved

Any further details:

Has the patient been withdrawn from the study?

- [ ] Yes
- [ ] No

Action taken with study drug (if applicable):

- [ ] None
- [ ] Dose reduced temporarily
- [ ] Dose reduced
- [ ] Dose discontinued temporarily
- [ ] Dose discontinued

**Important:** Once submitted:

- File original report form in Investigator Site File.
- Record in the patient’s hospital notes and Case Report Form (where applicable).
- Remember to update R&D when you update Sponsor

Date reported to R&D: [ ]

Name of person reporting: [ ]

Telephone number: [ ]

Please sign [ ]

For CTIMPS, PI signature: [ ]

Thank you.

Contact details for queries:
Lisella Wilkinson
QA Coordinator
Research & Development
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Ext 3056 or email lisella.wilkinson@nhs.net