CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

SAFETY REPORT TO RESEARCH ETHICS COMMITTEE

*Please indicate which type(s) of safety report you wish to notify with this cover sheet (tick all that apply). Use a separate sheet for notifications relating to different trials. Please send by email to the main REC for the trial concerned together with enclosures. For further guidance see:*

[*http://www.nres.npsa.nhs.uk/applicants/after-ethical-review/safetyreports/safety-reports-for-ctimps/*](http://www.nres.npsa.nhs.uk/applicants/after-ethical-review/safetyreports/safety-reports-for-ctimps/)

1. **Expedited report(s) of SUSAR in the UK***Notify only Suspected Unexpected Serious Adverse Reactions occurring in*

*the concerned trial at a UK site. SUSAR reports must follow the ICH E2B format.*

**2. Annual safety report / DSUR**

#### ASRs must follow the ICH E2F format for Development Safety Update Reports

#### (DSUR). Include a global list of all SSARs (Suspected Serious Adverse Reactions) related to the IMP and occurring in the reporting period.

#### **Other**

*For example, report of Data Monitoring Committee or other safety review.*

|  |  |
| --- | --- |
| Full title of study: |  |
| EudraCT number: |  |
| Research sponsor: |  |
| Name of Chief Investigator: |  |
| Name of main REC: |  |
| Main REC reference number: |  |

**Contact details for person making this notification**

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| Telephone: |  |
| Fax: |  |
| Email: |  |
| Date of this notification: |  |

### List of enclosed documents

Please list each report submitted with this notification (insert extra rows in table as required).

**1. Expedited SUSARs (UK only)**

|  |  |  |  |
| --- | --- | --- | --- |
| Sponsor’s report no. / reference | Trial site | Date SUSAR first reported to sponsor | Is this a 7 or 15 day report? |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

***2. Other reports***

|  |  |
| --- | --- |
| Type of report | Date of report |
|  |  |
|  |  |

**Acknowledgement of receipt by main REC (please insert name):**

The [ ]Research Ethics Committeeacknowledges receipt of the above.

|  |  |
| --- | --- |
| Signed: |  |
| Name: |  |
| Position on REC: |  |
| Date: |  |

*Signed original to be sent back only to the sponsor (or other person submitting the report).*

*Copy to be kept for information by main REC.*