# Appendix 1 - Adverse Events template

**WAHT Investigator’s Template for recording Adverse Events (Page 1 of 1)**

|  |  |  |  |
| --- | --- | --- | --- |
| Full title of Study: | | | |
| Ethics No: |  | WAHT Project Registration no: |  |

Sheet number : of

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| AE No: | Patient ID | Description of Event | | | Start date | Duration/End date | Outcome | \*\*Sequelae |
|  |  |  | | |  |  | Resolved  Ongoing  Ongoing with sequelae\*\* |  |
| Assessment | | | | | | | |
| Intensity: | | mild  moderate  severe | Expectedness | expected  unexpected i.e. not described in protocol, product information or  investigator brochure. | | | |
| Causality:  Relationship to study drug/device/intervention | | not related  unlikely to be related  possibly related  probably related  definitely related | Seriousness | Not serious  Results in death\*  Life threatening\*  Results in hospitalisation or prolongation of existing hospitalisation\*  Results in disability or incapacity\*  Congenital anomaly or birth defect\*  Other (please specify)\* | | | |
| AE No: | Patient ID | Description of Event | | | Start date | Duration/End date | Outcome | \*\*Sequelae |
|  |  |  | | |  |  | Resolved  Ongoing  Ongoing with sequelae\*\* |  |
| Assessment | | | | | | | |
| Intensity: | | mild  moderate  severe | Expectedness | expected  not expected i.e. not described in protocol, product information or  investigator brochure. | | | |
| Causality:  Relationship to study drug/device/intervention | | not related  unlikely to be related  possibly related  probably related  definitely related | Seriousness | Not serious  Results in death\*  Life threatening\*  Results in hospitalisation or prolongation of existing hospitalisation\*  Results in disability or incapacity\*  Congenital anomaly or birth defect \*  Other (please specify)\* | | | |

* Event is considered serious – report to the sponsor and WAHT R&D department within 24 hours using the form provided.

Where none is provided use the WAHT Research Related SAE/SUSAR Initial Report Form.

# Appendix 2 - Instructions for completion of SAE forms

Instructions Page 1 of 1

**RESEARCH RELATED SAE/SUSAR REPORT FORM**

**(drugs, devices and interventions)**

|  |
| --- |
| An event/reaction is serious if it:   * results in death, * is life threatening, * results in persistent or significant disability/incapacity, * requires hospitalisation, * prolongs a current hospitalisation * results in a congenital anomaly or birth defect. |

*This form must be used where WAHT is the sponsor of the research study in which the SAE has occurred or where no other form has been provided by the sponsor.*

Instructions for completion of Initial and Follow up Report Forms (Appendices 3 & 4):

1. As soon as possible, and at the latest within 24 hours of becoming aware of event,

* Complete the Initial Report Form and send to Sponsor.
* Where WAHT is sponsor;
  + Email (wnt-tr.ResearchMailbox@nhs.net) OR
  + fax (01934 881139)

one copy to the R&D Office

Please ensure that all sections have been completed.

1. As soon as possible, and at the latest within 5 days of becoming aware of the event,

* Complete the Follow up Report Form and send to Sponsor.
* Where WAHT is sponsor;
* Email (wnt-tr.ResearchMailbox@nhs.net) OR
* fax (01934 881139)

one copy to the R&D office

Please ensure that for SUSARs, all sections have been completed, and for other SAEs that sections 1, 2 and 3 have been completed.

**NB: Points 1 and 2 may be done together, if within 24 hours of becoming aware of the event.**

1. Complete and return (as above) further Follow-up Report Form(s) for data collected later than 5 days post SAE until the SAE has resolved or a decision for no further follow up has been taken.
2. Send a paper copy of the Initial and Full Report Forms with signatures to Sponsor. Where WAHT is sponsor send to the R&D Office, Weston General Hospital, Grange Road, Uphill, Weston-Super-Mare, BS23 4TQ (not required if signatures on faxed copy).
3. For multi-centre studies where CI is not investigator making this report, send a copy of each form to the Chief Investigator.
4. Send a copy each form to other bodies as required. e.g. Data safety monitoring board.
5. Keep original forms in Investigator Site File (ISF).

# Appendix 3 - SAE initial report form

|  |  |  |  |
| --- | --- | --- | --- |
| R&D use only: case reference number |  | Date report received by R&D |  |

**RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM**  (Page 1 of 4)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Person making report** | | | | | | | | | | | | | | | |
| Name: | |  | | | | | | | | | | | | | |
| Job title/role in study: | |  | | | | | | | | | | | | | |
| Contact address: | |  | | | | | | | | | | | | | |
| Email address: | |  | | | | | | | | | | | | | |
| Telephone No: | |  | | | | | | | | | | | | | |
| Fax number: | |  | | | | | | | | | | | | | |
| **2. Details of study** | | | | | | | | | | | | | | | |
| Full Title of Study: | | | | | | | | Study site (e.g.  Hospital name): | | | | | | | |
| WAHT R&D Project  Registration No: | | | | | | | |
| Ethics No: | | | | | | | |
| EudraCT No  (IMP studies only): | | | | | | | |
| **3. Details of subject affected by SAE/SUSAR** | | | | | | | | | | | | | | | |
|  |  | | | | Initials | DOB | | | | | Gender | | Weight | | Height |
| **4. Details of SAE/SUSAR** (further space available in section 12) | | | | | | | | | | | | | | | |
| Full description of event/reaction, including body site, reported signs and symptoms and diagnosis where possible: | | | | | | | | | | | | | | | |
| Event is defined as serious because it (tick as many as apply):  resulted in death  is/was life-threatening  resulted in persistent or significant disability/incapacity  required hospitalisation  prolonged an ongoing hospitalisation  resulted in a congenital anomaly or birth defect  other – please specify\*  **Please give further details in section 6 ‘Outcome’** | | | | | | | | | \*Specify: | | | | | | |
| **Maximum intensity (up until time of initial report)** | | | | Mild | | | | | | Moderate | | | | Severe | |
| **Onset Date**  **(**when event became serious) | | | **Onset Time** | **End date** | | | **End time** | | | | | ***OR* Duration** | | | |

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

|  |  |
| --- | --- |
| R&D use only: case reference number |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***To be completed by the person filling in the SAE form*** | | | | | |
| *WAHT R&D no.:* |  | *Subject ID/initials* |  | *Onset date of SAE* |  |

Appendix 3 **RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM** (Page 2 of 4)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **5. Details of IMP/device/intervention(s) if applicable** (further space available in section 12) | | | | | | |
| **Name of drug/device/intervention** | | **Total daily dose**  **(if applicable)** | | **Dosing regime (inc route)** | **Date/time of last dose/intervention** | |
|  | |  | |  |  | |
|  | |  | |  |  | |
|  | |  | |  |  | |
|  | |  | |  |  | |
|  | |  | |  |  | |
| **6. Outcome** (further space available in section 12) | | | | | | |
| Resolved\* | Ongoing\* | | Died\* (give cause and PM details if available) | | | |
| \*Give details: | | | | | | |
| Was the patient withdrawn from the study? | | | | Yes | | No |
| **7. Location of (onset of) SAE** (further space available in section 12) | | | | | | |
| Setting (e.g. hospital\*, home, GP, nursing home): | | | | | | |
| \*If SAE occurred on WAHT precinct give exact location: | | | | | | |
| **8. Action taken and further information** (further space available in section 12) | | | | | | |
| Please describe action taken: | | | | | | |
| Other information relevant to assessment of case e.g. medical history, family history, test results. | | | | | | |

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

|  |  |
| --- | --- |
| R&D use only: case reference number |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***To be completed by the person filling in the SAE form*** | | | | | |
| *WAHT R&D no.:* |  | *Subject ID/initials* |  | *Onset date of SAE* |  |

Appendix 3 **RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM** (Page 3 of 4)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **9. Causality and Expectedness (to be completed by physician)** | | | | |
| Is the SAE related to the drug/device/intervention?  Not related  Unlikely to be related  Possibly related\*  Probably related\*  Definitely related\* | | **\***If possibly, probably or definitely related, was the SAE unexpected?  Yes1  No2  (Unexpected means not described in the protocol or other product information) | | ***In addition to this form, and within 5 days:***  **1 - Please complete and return all sections of the follow up report form.**  **2 - Please complete and return sections 1, 2 and 3 of the follow up report form.** |
| **For blinded studies:**  Has the randomisation code been broken in making this assessment:  Yes\*  No  \*If yes, give details of randomisation: | | | | |
| **10. Sponsor notification (only complete where sponsor is not WAHT)** | | | | |
| Has the Sponsor been notified of the SAE/SUSAR? | | | Yes, give date:  No+ | |
| ***+Please note, you must inform the Sponsor within 24 hours of becoming aware of the event.*** | | | | |
| **11. Chief/Principal Investigator, or delegated physician (at this site)** | | | | |
| Name: |  | | | |
| Job title/role in study: |  | | | |
| Contact address: |  | | | |
| Email address: |  | | | |
| Telephone No: |  | | | |
| Fax number: |  | | | |
| Signature: |  | | | |
| I confirm that the contents of this form (pages 1, 2, 3 ± 4) are accurate and complete | | | | |

**Please tick this box if section 12 (next page) has been used:**

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

|  |  |  |  |
| --- | --- | --- | --- |
| R&D use only: case reference number |  | Date Received |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***To be completed by the person filling in the SAE form*** | | | | | |
| *WAHT R&D no.:* |  | *Subject ID/initials* |  | *Onset date of SAE* |  |

Appendix 3 **RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM** (Page 4 of 4)

|  |  |
| --- | --- |
| **12. Additional information (refer to section number)** | |
| Section no. | Further information |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

|  |  |  |  |
| --- | --- | --- | --- |
| R&D use only: case reference number |  | Date Received |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***To be completed by the person filling in the SAE form*** | | | | | |
| *WAHT R&D no.:* |  | *Subject ID/initials* |  | *Onset date of SAE* |  |

# Appendix 4 - SAE follow up report form

**RESEARCH RELATED SAE/SUSAR FOLLOW UP REPORT FORM** (Page 1 of 3)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **1. Further details of SAE/SUSAR** | | | | | | |
| Further details of event/reaction, including body site, reported signs and symptoms and diagnosis where possible: | | | | | | |
| **Maximum intensity (up until time of follow up report)** | | Mild | | Moderate | | Severe |
|  | | **End date** | | **End time** | | ***OR* Duration** |
| **2. Outcome** | | | | | | |
| Resolved\* | Ongoing\* | Died\* (give cause and PM details if available) | | | | |
| \*Give details: | | | | | | |
| Was the patient withdrawn from the study? | | | Yes | | No | |
| **3. Additional action taken and further information since initial report** | | | | | | |
| Please describe further action taken: | | | | | | |
| Further information or missing data relevant to assessment of case e.g. medical history, family history, test results. | | | | | | |

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

**Name (please print):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Job title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |
| --- | --- |
| Signature of Chief /Principal Investigator or delegated physician: |  |
| Name (print please): | |
| I confirm that the contents of this form (pages 1± 2/3) are accurate and complete | |

**Appendix 4**

|  |  |
| --- | --- |
| R&D use only: case reference number |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *To be completed by the person filling in the SAE form* | | | | | |
| *WAHT R&D number:* |  | *Subject ID/initials* |  | *Onset date of SAE* |  |

**RESEARCH RELATED SAE/SUSAR FOLLOW UP REPORT FORM** (Page 2 of 3)

Sheet number: of

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **4. CONCOMITANT MEDICATION** –details of administration of other medication concurrent with the IMP(s)/device/intervention. | | | | | | | | |
| Brand name: | Indication | Route  (e.g. oral) | Form  (e.g. tablet) | Total dose/24h  (specify units) | Regimen (e.g. BD) | Start date  & time | Stop date  & time | *Or* duration of treatment |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

**Continue on new sheet if necessary; please identify how many sheets have been used.**

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

**Appendix 4**

|  |  |
| --- | --- |
| R&D use only: case reference number |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *To be completed by the person filling in the SAE form* | | | | | |
| *WAHT R&D number:* |  | *Subject ID/initials* |  | *Onset date of SAE* |  |

**RESEARCH RELATED SAE/SUSAR FOLLOW UP REPORT FORM** (Page 3 of 3)

Sheet number: of

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **5. STUDY IMP** – details of administration. **NB complete for IMP studies only** | | | | | | | | | | | | | |
| Brand name: | Indication | Batch no. | Route  (e.g. oral) | Form  (e.g. tablet) | | Total dose/24h  (specify units) | | | Regimen (e.g. BD) | | Start date  & time | Stop date  & time | *Or* duration of treatment |
|  |  |  |  |  | |  | | |  | |  |  |  |
|  |  |  |  |  | |  | | |  | |  |  |  |
|  |  |  |  |  | |  | | |  | |  |  |  |
|  |  |  |  |  | |  | | |  | |  |  |  |
|  |  |  |  |  | |  | | |  | |  |  |  |
| For blinded studies, was the randomisation code broken? | | | | |  | | \*Yes |  | | No | | | |
| \*If yes, give details: | | | | | | | | | | | | | |

**Continue on new sheet if necessary; please identify how many sheets have been used.**

**Name of person completing report:**

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

# Appendix 5 - SAE/SUSAR Sponsor report form

Page 1 of 1

**SAE/SUSAR SPONSOR REPORT FORM**

|  |
| --- |
| **This page for R&D Use Only** |
| **WAHT sponsored Studies** |

|  |  |
| --- | --- |
| Case reference number |  |
| WAHT Project Registration No: |  |
| EudraCT No (IMP trials only): |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **1. Sponsor assessment of causality** | | | |
| Is the SAE related to the drug/device/intervention?  Not related  Unlikely to be related  Possibly related\*  Probably related\*  Definitely related\* | **\***If possibly, probably or definitely related, was the SAE unexpected?  Yes1  No2  (Unexpected means not described in the protocol or other product information) | | 1 - Ensure all required sections of the follow up report form have been completed.  2 - Ensure sections 1, 2 and 3 of the follow up report form have been completed. |
| Comments: | | | |
| Name of person performing sponsor assessment[[1]](#footnote-1): | | Contact Number: | |
| Signature of person performing sponsor assessment: | | Date: | |

|  |  |
| --- | --- |
| **2. Administrative and sponsor details** | |
| Date report received from investigator: | CTA/DDX number (if applicable): |
| Name and Address of sponsor:  Weston Area Health Trust  R&D Department  Grange Road  Uphill  Weston-Super-Mare  BS23 4TQ | Contact person at Sponsor  Name:  Address: Same as sponsor.  Telephone no: 01934 881135  Fax no: 01934 881139 |

# Appendix 6 - Guidance on content of annual safety reports

*For Annual Safety Report Form go to Appendix 7.*

The safety report of a clinical trial should have three parts:

* + A report on the subjects’ safety in the concerned clinical trial.
  + A line listing of all suspected SARs (including all SUSARs) occurred in the concerned trial.
  + An aggregate summary tabulation of suspected SARs that occurred in the concerned trial.

1. **Report on the subjects’ safety of a clinical trial**

Based on the information provided by investigators and the sponsor’s own assessments, the sponsor will report all new findings related to the safety of the IMP treatments in the concerned trial. The concept of new findings refers to information not already present in the investigator’s brochure or, for licensed drugs, the summary of product characteristics. When relevant, the following points should be considered:

1. relation with dose, duration, time course of the treatment
2. reversibility
3. evidence of previously unidentified toxicity in the trial subjects
4. increased frequency of toxicity
5. overdose and its treatment
6. interactions or other associated risks factors
7. any specific safety issues related to special populations, such as the elderly, the children or any other at risk groups.
8. positive and negative experiences during pregnancy or lactation
9. abuse
10. risks which might be associated with the investigation or diagnostic procedures of the clinical trial

The report should also consider other experiences with the investigational medicinal product that are likely to affect the subjects' safety. It should detail the measures previously or currently proposed to minimise the risks found where appropriate. Finally, a rationale must be given on whether or not it is necessary to amend the protocol, to change or update the consent form, patient information leaflet and the investigator’s brochure. This report will not replace the request for protocol amendments, which will follow its own specific procedure.

1. **Line-listings**

The annual report should contain a trial-specific line-listing of all reports of suspected SARs that were reported during this trial. The line listing provides key information but not necessarily all the details usually collected on individual cases. It should include each subject only once regardless of how many adverse reaction terms are reported for the case. If there is more than one reaction, they should all be mentioned but the case should be listed under the most serious adverse reaction (sign, symptom or diagnosis) as judged by the sponsor. It is possible that the same subject may experience different adverse reactions on different occasions. Such experiences should be treated as separate reports. In such circumstances, the same subject might then be included in a line listing more than once and the line-listings should be cross-referenced when possible. Cases should be tabulated by body system (standard system organ classification scheme). The line listing identifiable by the sponsor listing reference number or date and time of printing should include the information per case as described in 2.1. Usually there should be one listing for each trial, but separate listings might be provided for active comparator or placebo or when appropriate and relevant for other reasons, e.g. in the case that in the same trial for different formulations, indications or routes of administration are studied.

* 1. **Content of line listing**

The line listing identifiable by the sponsor listing reference number or date and time of printing should include the following information per case:

1. clinical trial identification
2. Study subjects identification number in the trial
3. case reference number (Case-ID-Number) in the sponsor’s safety database for medicinal products
4. country in which case occurred
5. age and sex of trial subject
6. daily dose of investigational medicinal product, (and, when relevant, dosage form and route of administration)
7. date of onset of the adverse reaction. If not available, best estimate of time to onset from therapy initiation. For an ADR known to occur after cessation of therapy, estimate of time lag if possible.
8. dates of treatment (if not available, best estimate of treatment duration.)
9. adverse reaction: description of reaction as reported, and when necessary as interpreted by the sponsor, where medically appropriate, signs and symptoms can be lumped into diagnoses. MedDRA should be used.
10. patient’s outcome (e.g. resolved, fatal, improved, sequelae, unknown). This field should indicate the consequences of the reaction(s) for the patient, using the worst of the different outcomes for multiple reactions
11. comments, if relevant (e.g. causality assessment if the sponsor disagrees with the reporter; concomitant medications suspected to play a role in the reactions directly or by interaction; indication treated with suspect drug(s); dechallenge/rechallenge results if available)
12. unblinding results in the case of unblinded SUSARs expectedness at the time of the occurrence of the suspected SARs, assessed with the reference document (i.e. investigator’s brochure) in force at the beginning of the period covered by the report.
13. **Aggregate summary tabulations**

In addition to individual cases line listings, summary tabulations of SAR terms for signs, symptoms and/or diagnoses across all patients should usually be presented to provide an overview for the trial. These tabulations ordinarily contain more terms than subjects. When the number of cases is very small, a narrative description would be more suitable.

The aggregate summary tabulation should specify the number of reports:

1. for each body system
2. for each ADR term
3. for each treatment arm, if applicable (IMP, comparator or placebo, blinded treatment)

The unexpected ADR terms should be clearly identified in the tabulation. As an example, the table shown in section 3.1 can be used.

* 1. **Example for an Aggregate Summary Tabulation**

Number of reports by terms (signs, symptoms and diagnoses) for the trial number ………

*(An \* indicates an example of a SUSAR)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Body system /ADR term** | **Verum** | **Placebo** | **Blinded** |
| ***CNS***  Hallucinations\*  Confusion\* | 2  1 | 2  1 | 0  0 |
| Sub-total | 3 | 3 | 0 |
| ***CV*** |  |  |  |
| Sub-total |  |  |  |

# Appendix 7 – Annual Safety Report Form

**ANNUAL SAFETY REPORT FORM FOR IMP STUDIES – WAHT SPONSOR – UK STUDIES**

*Instructions for Researchers*

1. One year following the granting of a Clinical Trials Authorisation Certificate, and thereafter annually**[[2]](#footnote-2)**, complete sections 1-5 of the Annual Safety Report Form - IMP Studies – WAHT Sponsor – UK.
2. In addition, complete Safety Report form for CTIMPs available at: http://www.nres.npsa.nhs.uk/docs/forms/Safety\_Report\_Form\_(CTIMPs).doc
3. *If there have been no reports of any Serious Adverse Events:*

Cross through section 6 and mark as not required. Sign and date comment.

Send the completed forms to:

* + Medicines and Healthcare products Regulatory Agency (MHRA), Clinical Trials Unit, 12-2, MHRA, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.
  + The Research Ethics Committee that granted approval (NB an annual progress report may also be required. See section 4.5 of the WAHT Research Related Adverse Event Reporting Policy).
  + WAHT R&D Department, Grange Road, Uphill, Weston-Super-Mare, BS23 4TQ

1. *If SAEs have been reported during the study:*
   * 1. Send part completed forms to the WAHT R&D Department, Grange Road, Uphill, Weston-Super-Mare, BS23 4TQ

*Instructions for R&D Department*

1. On receipt of a part completed Annual Report Form, complete ‘Causality’ and ‘Expectedness’ columns for all SSARs reported to the WAHT and where an unblinded assessment has been performed by the WAHT.
2. Completed section 6.
3. Send the completed forms to:

* Medicines and Healthcare products Regulatory Agency (MHRA), Clinical Trials Unit, 12-2, MHRA, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.
* The Research Ethics Committee that granted approval.

1. Inform CI. NB Do not provide the CI with any information that could unblind and compromise the study.

Appendix 7 **ANNUAL SAFETY REPORT FORM - IMP STUDIES – WAHT SPONSOR - UK**

*(Page 1 of 4 unless stated otherwise)*

*Page of*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1. Details of Sponsor** | | | | | |
| Organisation: |  | | | | |
| Name of person to contact: |  | | | | |
| Contact address: |  | | | | |
| Email address: |  | | | | |
| Telephone No: |  | | | | |
| Fax number: |  | | | | |
| **2. Details of person making report (if different to above)** | | | | | |
| Name: |  | | | | |
| Job title/role in study: |  | | | | |
| Contact address: |  | | | | |
| Email address: |  | | | | |
| Telephone No: |  | | | | |
| Fax number: |  | | | | |
| **3. Details of study** | | | | | |
| WAHT R&D Project  Registration No: |  | | Ethics No: | |  |
| EudraCT No: |  | | CTA No:  (If CTA not yet issued, DDX no.) | |  |
| Full Title of Study: | | | | | |
| Date of MHRA approval: | |  | | | |
| **4. Summary of Serious Adverse Events (SAEs)** | | | | | |
| Number of SAEs | In reporting year: | | | In total: | |
| No. of SSARs | In reporting year: | | | In total: | |
| No. of SUSARs | In reporting year: | | | In total: | |

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

|  |  |  |  |
| --- | --- | --- | --- |
| WAHT R&D Project  Registration No: |  | Ethics No: |  |
| EudraCT No: |  | CTA No:  (If CTA not yet issued, DDX no.) |  |

Appendix 7 **ANNUAL SAFETY REPORT FORM - IMP STUDIES – WAHT SPONSOR - UK**

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|  |  |
| --- | --- |
| **4. Report on subjects’ safety in CTIMP** | |
| Are there any new findings[[3]](#footnote-3) related to the safety of the IMP treatments in this trial? | Yes  No |
| If yes, provide details[[4]](#footnote-4): | |
| Have there been any other experiences with this IMP that could affect the subjects’ safety? | Yes  No |
| If yes, provide details[[5]](#footnote-5): | |
| Is it necessary to amend the protocol, patient information sheet, consent form or investigator brochure? | Yes  No |
| If yes, give details and rationale: | |

**Signature of person making report:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_/\_\_\_\_/\_\_\_\_**

1. Where the assessment has been performed by the Data Safety Monitoring Board, give the name of the Chair and attach a list of names of the members of the Board who participated in the assessment. [↑](#footnote-ref-1)
2. For clinical trials that commenced before 1 May 2004, the reporting period starts with the issue date of the CTX letter or first DDX exemption letter by the MHRA (or previously by the Medicines Control Agency). [↑](#footnote-ref-2)
3. New findings refers to information not already present in the investigator’s brochure or for licensed drugs the summary of product characteristics. [↑](#footnote-ref-3)
4. When relevant, the following points should be considered: relation with dose, duration, time course of the treatment; reversibility; evidence of previously unidentified toxicity in the trial subjects; increased frequency of toxicity; overdose and its treatment; interactions or other associated risks factors; any specific safety issues related to special populations, such as the elderly, the children or any other at risk groups; positive and negative experiences during pregnancy or lactation; abuse; risks which might be associated with the investigation or diagnostic procedures of the clinical trial. [↑](#footnote-ref-4)
5. When relevant, the following points should be considered: relation with dose, duration, time course of the treatment; reversibility; evidence of previously unidentified toxicity in the trial subjects; increased frequency of toxicity; overdose and its treatment; interactions or other associated risks factors; any specific safety issues related to special populations, such as the elderly, the children or any other at risk groups; positive and negative experiences during pregnancy or lactation; abuse; risks which might be associated with the investigation or diagnostic procedures of the clinical trial. [↑](#footnote-ref-5)