**JOINT RESEARCH & ENTERPRISE SERVICES**

**SERIOUS ADVERSE EVENT REPORTING FORM**

**email** [**adverseevents@sgul.ac.uk**](mailto:adverseevents@sgul.ac.uk)within 1 working day of identification of event

**Section A:** Study Information Initial Report or Follow upnumber…..?

|  |  |  |  |
| --- | --- | --- | --- |
| Study name: | | EudraCT ID: | |
| Sponsor Ref: | | Chief Investigator: | |
| Sponsor : SGH or SGUL | REC Reference: | | Reporting Site ID: |
| Site name : | | Study Site PI: | |

**Section B:** Patient information

|  |  |  |  |
| --- | --- | --- | --- |
| Patients Trial/study ID: |  | Patient’s weight (kg) : | tick if not known |
| Patient’s height (m) : | tick if not known | Patient’s Gender: |  |

|  |
| --- |
| ***For JRES Office Use Only***  SAE Reference  Date Received  Type of Report |

**Section C:**  Case description

Provide details of the adverse event which prompted this report

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Provide the event term which prompted this report\* | Severity\*\* | Date of onset  dd/mm/yy | | SAE status  1 = resolved  2= Resolved with sequelae (Specify)  3= on-going  4= worsened  5 = fatal | | Date Resolved  dd/mm/yyyy |
|  |  |  | |  | |  |
| Please select the reason for reporting (if multiple reasons, select all that apply)  1 = Resulted in death  2 = Life threatening  3 = Required in-patient hospitalisation or prolongation of existing hospitalisation◊  4 = Persistent or significant disability/incapacity  5 = Congenital anomaly/defect  6 = Other important medical condition please specify………………………… | | | | | | |
| Date PI or site was notified or became aware of SAE : | | ◊If hospitalised, provide: | Admission date:  tick if prior to event (date not required) | | Discharge date: | |

\*Adverse event term should be provided with reference to the DAIDS v2.1 terms unless the study protocol and documentation indicates otherwise.

\*\* If the need arises to grade an AE that is not identified in the DAIDS AE grading table, the study protocol or accompanying documentation. The following definitions should be used:

Grade 1- MILD- Mild symptoms cause no or minimal interference with usual social and functional activities with intervention not indicated. The event is easily tolerated. Grade 2- MODERATE- Moderate symptoms cause greater than minimal interference with usual social & functional activities with intervention indicated, Grade 3- SEVERE- Severe symptoms cause an inability to perform usual social & functional activities with intervention or hospitalisation indicated. Grade 4-POTENTIALLY LIFE-THREATENING-Symptoms causing inability to perform basic self-care functions OR Medical or operative intervention indicated to prevent permanent impairment, persistent disability or death. If severity could fall under either one of two grades, select the higher of the two grades.

Provide details of any other event(s) relevant to the SAE

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Event \* | Severity\*\* | Date of onset  dd/mm/yyyy | SAE status  1 = resolved  2= Resolved with sequelae (Specify)  3= on-going  4= worsened  5 = fatal | Date Resolved  dd/mm/yyyy |
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**Section D:** IMP or Study drug information

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| Trial drug  Frequency and dose | Is the study blinded ? | Date of 1st administration  dd/mm/yy | Date of most recent administration  dd/mm/yy | Actual dose given at most recent administration  Provide with units and frequency | Route  1 = oral  2 = Intravenous  3= Subcutaneous  4= Intramuscular  5 = other – specify | Study arm/cycle | Causal relationship to SAE  1 = Definitely  2 = Probably  3= Possibly  4 = Unlikely  5 = Not related  6 = Not assessable | Expectedness  Was the event one of the recognised undesirable effects of trial medication #  1 = expected  2 = unexpected | Action taken due to SAE  1 = None  2= dose reduction  3 = Treatment delayed  4 = Treatment reduced and delayed  5 = Treatment stopped  6 = Code Break (blinded studies only) |
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# Expectedness assessment should only be performed when code 1, 2 or 3 is recorded in the causal relationship column

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| --- | --- | --- | --- | --- | --- |
| Describe Serious adverse event and relevant medical history | | | | | |
| Diagnostic tests : Please attach reports Number of reports attached | | | | | |
| Test Name |  |  |  |  |  |
| Date |  |  |  |  |  |
| Normal range |  |  |  |  |  |
| Result (+ units) |  |  |  |  |  |

**Section E:** Concomitant medication

Use this section to provide details of concomitant medication taken at time of the event and any medication taken to treat event

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| --- | --- | --- | --- | --- | --- | --- |
| Name of medication (generic name where possible) | Total Daily Dose | Route  1 = oral  2 = Intravenous  3= Subcutaneous  4= Intramuscular  5 = other – specify | Indication for prescription | Start Date  dd/mm/yy | Ongoing  1 = yes  2 = No | End date  dd/mm/yy |
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|  |  |  |  |  |  |  |
| Do you consider this event likely to have been caused by anything other than the treatments listed previously on this form  1= yes 2 = No | | | | | | |
| If yes specify : including medical history, drug or alcohol abuse, non-drug treatment, family history or findings from special investigations | | | | | | |

**Section F**: Details of person completing the form

|  |  |
| --- | --- |
| Signature of person completing form\*\*\* | Date |
| Signature of investigator performing causality and expectedness assessment \*\*\* | Date |

\*\*\*You must have signed the delegation log

**Section G**: This section should be completed by the Sponsor’s Representatives

|  |  |  |  |
| --- | --- | --- | --- |
| Provide further comment and revised scores if sponsor’s clinical representative does not agree with site causality and/or expectedness assessment | | | |
| JRES Reviewer | Date SAE notification first received by JRES | | Date Checked by JRES Reviewer |
| SAE SAR SUSAR: 7 DAY SUSAR 15 DAY | | | |
| Code Break Requested (for blinded studies Only) by whom:  tick if not applicable | | Date Code break performed:  NB- CONSULT PROTOCOL TO CONFIRM WHOM TREATMENT ALLOCATION CAN BE REVEALED TO – DO NOT ATTACH TO THIS REPORT IF COPY RETURNED TO TMF. tick if not applicable | |
| If SUSAR – Date reported to MHRA  tick if not applicable | |  | |
| CI Informed: Y/N | | Date CI informed: | |