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| **Adverse Event of Special Interest (AESI) reporting form**  **THIS FORM NEEDS ADAPTING TO BE STUDY SPECIFIC BEFORE USE** | | | | | | |
| Once you have become aware of an **AESI,** please scan & email this signed form to [research.safety@qmul.ac.uk](mailto:research.safety@qmul.ac.uk) (or to the trial co-ordinator’s email or fax number if multi-site study) WITHIN 24 hours of learning of the event. | | | | | | |
| Report type: | Initial  Follow-up | | | | | |
| What are you reporting? | AESI |  | | | | |
| SAR or SAE  SUSAR\* Pregnancy | **This is the incorrect form**  **Please consult your sponsor contact** | | | | |
|  |  | | | | |
| **If the study is multi-site, the section below should be completed by the main site trial coordinator prior to sending the template to the sites** | | | | | | |
| Full title of the trial: |  | | | | | |
| Sponsor: | Barts Health  Queen Mary | | | | | |
| IRAS Number: |  | | | | | |
| Public Database Number: |  | | | | | |
| Chief investigator: | Name:  Email:  Phone Number: | | | | | |
| Name of ALL IMPs | IMP 1: |  | | | | |
| IMP 2: |  | | | | |
| IMP 3: |  | | | | |
| IMP 4: |  | | | | |
| Is the treatment blinded for this study? | Yes  No | | | | | |
| **This section should be completed by the SITE:** | | | | | | |
| Subject identification code: |  | | Patient initials | |  | |
| Patient’s age at time of event: |  | | Sex: | | M  F | |
| Treatment allocation (if applicable): | <<Coordinator: before distribution, list each arm or cohort with tick box as per example below>>  Arm A (Drug name)  Arm B (Drug name) | | | | | |
| Principal investigator: | Name:  Email:  Phone Number: | | | | | |
| Study coordinator local site: | Name:  Email:  Phone Number: | | | | | |
| Name of reporting host institution: | Site name:  Site number: | | | | | |
| Date of site becoming aware of the event: | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | | | | |
| Onset date of AESI: | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | Resolution date of SAE: | | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | |
| Event description (please use MedDRA terminology):  *(please use a separate form for each event)* | This section might be adapted to a choice or list of only the events listed as AESI’s in the protocol | | | | | |
| Narrative:  (A summary of signs and symptoms, diagnosis, treatment of event, concurrent treatment, other relevant medical history, including re‐challenge details if applicable. Please include the point in the study at which the event occurred). |  | | | | | |
| Severity: | Mild  Moderate  Severe | | | | | |
| Is the AESI due to the progression of an underlying illness? | Yes  No | | | | | |
| Is the AESI related to the trial conduct? | Yes  No | | | | | |
| Is the AESI likely to be a reaction to one of the IMPs in the study? | <<Insert IMP 1>> | | | | Reasonably possible | Not reasonably possible |
| <<Insert IMP 2>> | | | | Reasonably possible | Not reasonably possible |
| Is the AESI expected? *Expected reactions will be found in the <<INSERT RSI>>* | <<Insert IMP 1>> | | | | Expected | Unexpected |
| <<Insert IMP 2>> | | | | Expected | Unexpected |
| Did the PI withdraw the patient from the trial? | Yes  No | | | | | |
| Outcome of AESI | Recovered | | | | | |
| Recovering | | | | | |
| Not recovered | | | | | |
| Recovered with sequelae | | | | | |
| Unknown | | | | | |
| Fatal \* if a AESI is fatal it should become an SAE unless otherwise specifically agreed MHRA | | | Specify date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | |
| Please state whether the death was expected (e.g. disease progression, or if earlier than expected. Provide explanation): | | | | | |
| Person completing the form if not the PI | Name:  Medical profession (i.e. doctor or dentist):  Email:  Phone Number:  Signature: Date: | | | | | |
| Investigator’s Name | Print | | | | | |
| Investigator’s Signature |  | | | | Date: | |

**Sponsor Medical Assessor only - AESI**

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| --- | --- |
| Date form RECEIVED by CI’s team from external site:  \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | Reviewed by:  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) |
| Date form REVIEWED by CI (or delegate):  \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | CI (or delegate) signature:  Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) |
| Does CI (or delegate) agree with relatedness assessment? Yes  No  If No, please comment: | |
| Does CI (or delegate) agree with expectedness assessment? Yes  No  If No, please comment: | |