|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Once you have become aware of an SAE or SUSAR, 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 fax number if multi-site study) WITHIN 24 hours of learning of the event. For SUSARs ensure that the protocol is reviewed and all relevant documentation is sent accordingly (see safety reporting section in protocol). | | | | | | |
| Report type: | Initial  Follow-up | | | | | |
| What are you reporting? | SAR or SAE |  | | | | |
| SUSAR\* | (\*Note: If you are reporting a SUSAR the randomisation code for this patient will have to be unblinded) | | | | |
| Pregnancy | (if so please use the separate pregnancy reporting form) | | | | |
| **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 Study: |  | | | | | |
| Sponsor: | Barts Health  Queen Mary | | | | | |
| IRAS Number: |  | | | | | |
| EudraCT 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: | | | | | |
| Trial 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 SAE: | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | Resolution date of SAE: | | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | |
| Event description (please use MedDRA terminology):  *(please use a separate form for each event)* |  | | | | | |
| 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 | | | | | |
| Type of SAE  (If there is more than one criterion, choose the more/most significant one. Seriousness is a regulatory definition and should not be confused with severity). | Results in death | | | | | |
| Life threatening | | | | | |
| Hospitalisation or prolonged | | | | | |
| Persistent or significant disability or incapacity | | | | | |
| Congenital anomaly or birth defect | | | | | |
| “Other” important medical event  If “Other” please describe: | | | | | |
| Is the SAE due to the progression of an underlying illness? | Yes  No | | | | | |
| Is the SAE related to the study conduct? | Yes  No | | | | | |
| Is the SAE 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 SAR expected? *Expected reactions will be found in the <<INSERT RSI/IB/SmPC version and date used to assess this >>* | <<Insert IMP 1>> | | | | Expected | Unexpected |
| <<Insert IMP 2>> | | | | Expected | Unexpected |
| Is the event classified as a SUSAR (i.e. RELATED to one of the IMPs and UNEXPECTED)? | Yes  No | | | | | |
| Did the PI withdraw the patient from the study? | Yes  No | | | | | |
| Outcome of SAE | Recovered | | | | | |
| Recovering | | | | | |
| Not recovered | | | | | |
| Recovered with sequelae | | | | | |
| Unknown | | | | | |
| Fatal | | | 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 - SAE**

|  |  |
| --- | --- |
| 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: | |

**Additional information if SUSAR**

If this event is a SUSAR please complete the additional form and submit with the SAE form

Initial report  Follow-up information

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Participant details** | | | | | | |
| Participant weight | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_kg | | | | | |
| Participant height | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_cm | | | | | |
| Country of origin of the SUSAR |  | | | | | |
| Please enter details of any prior diseases the participant has suffered that are not being treated by the study medication (please use MedDRA terms where possible) | Disease name | | | Start date | | End date |
| 1.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Continuing?  Yes  No  Unknown | | | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) |
| 2.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Continuing?  Yes  No  Unknown | | | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) |
| 3.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Continuing?  Yes  No  Unknown | | | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) |
| 4.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Continuing?  Yes  No  Unknown | | | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) |
| In relation to the reaction, list here the relevant test(s) performed | Test | | | Result (including unit) | | Date of test |
|  | | |  | |  |
|  | | |  | |  |
|  | | |  | |  |
|  | | |  | |  |
| **Medication details** | | | | | | |
| Please enter details of all medication the study participant has taken in the last 3 months, **including non-study medication and study medication**. Each medication should be characterised as either ‘Suspect’ or ‘Concomitant’. | | | | | | |
| **Medication 1:** | | | | | | |
| **Name of drug** (generic) |  | | | | | |
| Dose |  | | | | | |
| Drug characterisation | Suspect  Concomitant | | | | | |
| Drug dose unit |  | | | | | |
| Drug dose interval |  | | | | | |
| Form (tablet/solution etc.) |  | | | | | |
| Route of administration |  | | | | | |
| Indication |  | | | | | |
| Start date | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | End date | | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | |
| Action taken | Drug withdrawn  Dose reduced  Dose increased |  | | Dose not changed  Unknown  Not applicable | |  |
| Batch number, if IMP |  | | | | | |
| Principal investigator assessment | Reasonably possible |  | | Not reasonable possible | |  |
| CI assessment | Reasonably possible |  | | Not reasonable possible | |  |
|  | | | | | | |
| **Medication 2:** | | | | | | |
| **Name of drug** (generic) |  | | | | | |
| Dose |  | | | | | |
| Drug characterisation | Suspect  Concomitant | | | | | |
| Drug dose unit |  | | | | | |
| Drug dose interval |  | | | | | |
| Form (tablet/solution etc.) |  | | | | | |
| Route of administration |  | | | | | |
| Indication |  | | | | | |
| Start date | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | | End date | | \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  (date) (month) (year) | |
| Action taken | Drug withdrawn  Dose reduced  Dose increased |  | | Dose not changed  Unknown  Not applicable | |  |
| Batch number, if IMP |  | | | | | |
| Principal investigator assessment | Reasonably possible |  | | Not reasonable possible | |  |
| CI assessment | Reasonably possible |  | | Not reasonable possible | |  |