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| **Summary** |  |
| Report type | Choose from the following:  ***Initial Report***  - If this is the first time you are sending notification of the event of the event.  ***Follow up Report***  - If this is a follow up report on an event. A follow up report is necessary if there is no stop date i.e. event is “ongoing” at the time the initial report was sent, or if the outcome is “continuing”. |
| Criteria for definition of SAE | Choose from the following.  ***Subject Died***  ***Life threatening***  ***In-patient hospitalization or prolongation***  ***Persistent or significant disability***  ***Congenital anomaly/birth defect***  ***Medically important event***  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. |
| Chief Investigator’s name | Note: The Chief Investigator (CI) is the person identified as CI in the ethics application form and can be defined as:  (a) in relation to a clinical trial conducted at a single trial site, the investigator for that site or (b) in relation to a clinical trial conducted at more than one trial site, the investigator who takes primary responsibility for the conduct of the trial whether or not he is an investigator at your site. |
| Date of SAE awareness | Enter date the first member of the study team is aware of the SAE |
| Start date of SAE | Enter the date the event became serious |
| Stop date of SAE or state if ongoing | Enter the date the event ceased to be serious e.g. if hospitalization, date of discharge. If the event is ongoing, there should be a follow up report when there is a stop date or when significant changes occur. |
| Keywords *(SAE Diagnosis or main symptoms)* | Enter keywords that best summarize the event. Common medical terms may be used. |
| Subject initials | Enter subject initials. Do not enter subject name or any information that will reveal the subject’s personal identity. |
| Subject ID | Enter unique subject code or reference number |

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| 1. **Narrative** |  |
| Please provide an account of the event, similar in format to that of a discharge summary. The description must have sufficient details for evaluation by the individuals reviewing the SAE who may not be experts in the disease area or investigational medicinal products (IMPs). Mention and summarize any relevant lab data or diagnostic tests. | |

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| **3. Evaluation of Event** | |
| Outcome | Choose from the following. If the outcome is “continuing”, please provide a follow up SAE report when status has changed.  ***Recovered***  ***Recovered with sequalae***  ***Continuing***  ***Patient died***  ***Change in AE***  ***Unknown*** |
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| Severity | Choose from the following. This should not be confused with seriousness, which has a regulatory definition.  ***Mild***  ***Moderate***  ***Severe*** |
| Action taken with study drug | Choose from the following.  ***None***  ***Dose temporarily reduced***  ***Dose reduced***  ***Discontinued temporarily***  ***Discontinued*** |
| Other action | Choose from the following. If “treated with medication” or “other”, you may attach supplemental pages if applicable.  ***None***  ***Treated with medication***  ***Other*** |

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| **4. Subject Details** | Self explanatory |

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| **5. Study Drug(s)**  Enter details of IMP(s) involved. This section must be completed regardless of whether there is a causal relationship with the study drug(s). |

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| 6. Death Details *(if patient died)*  Cause of death obtained from | Choose from the following  ***Working diagnosis***  ***Coroner’s inquest***  ***Death certificate*** |

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| **7. Relevant Medical/Surgical History** | |
| If no CRF pages attached, describe relevant medical history | Please attach relevant CRF pages. If not, describe relevant medical history. The description must have sufficient details for evaluation by the individuals reviewing the event who may not be experts in the disease area. |

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| **8. Concomitant Medication** | |
| If no CRF pages attached, describe details of conc meds | Please attach relevant CRF pages. If not, describe relevant details of concomitant medication e.g. drug name (generic preferred), dose, route, indication, start date and stop date (if applicable). |

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| **9. Study Details** |  |
| Study Design | Choose from the following  ***Open***  ***Single blind***  ***Double blind*** |

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| **10. Principal Investigator Details** | Self Explanatory |
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| **11. Signature of Reporter** | Note: The reporter is the person filling out the main body of the report. |

**12. Causality and Expectedness**

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| Evaluation of causal relationship with suspect drug | Choose from the following:  ***Related***  - If the causal relationship between the IMP and the SAE is at least a reasonable possibility, i.e., the relationship cannot be ruled out.  ***Not Related***  - If there is no causal relationship between the IMP and the SAE i.e. the event is caused by something other that the IMP e.g. underlying disease, a concomitant medication. |
| If the causal relationship is not clear, please indicate how you came to your decision. | Provide details that are relevant for evaluation of causality by the individuals reviewing the SAE who may not be experts in the disease area or IMP(s). |
| Expectedness  Signature of Medically  Qualified Investigator | The assessment of ‘expectedness’ should be made through direct reference to the current product information: the current version of the Investigator Brochure (IB) if the product is unlicensed, or the latest version of the Summary of Product characteristics (SmPC) for licensed products. The most recent SmPCs are available at <http://emc.medicines.org.uk>  Note: May be a different person from the reporter named in section 11 |

**Remember to sign the form before submitting**