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| **Study Name:** Insert details | |
| EudraCT /IRAS reference (if CTIMP): Insert details  REC reference (if non-CTIMP): Insert details | SAE Identifier: |
| **Site name:** | **Type of Report:**  Initial  or Follow up  Number: \_\_ |
| **Principal Investigator name:** |

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| **Participant ID:** (unique participant study code or reference number) | |
| Age: | Height (if relevant): |
| Male  Female | Weight (if relevant): |

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| **Details of SAE** | |
| **Why was the event Serious?**  resulted in death,  is life threatening,  requires inpatient hospitalisation or prolongation of existing hospitalisation,  persistent or significant disability/incapacity,  congenital anomaly/birth defect,  other important medical event. | **Date of SAE awareness at site: \***     |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  | / |  |  |  |  |   (dd/mm/yyyy)   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | : |  |  |   (hh:mm 24 hour clock)  \*If reported late confirm reason for lateness in the additional information section below. |

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| **Main SAE diagnosis**  (Enter the MAIN EVENT TERM, the medical term that best summarises the event) | **Grade or Severity**  (CTCAE or in protocol) | **Date SAE started**  dd/mm/yyyy | **SAE status**  See code list A | **Date SAE ceased to be serious**  dd/mm/yyyy |
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| **Narrative** (provide an account of the event including any associated symptoms. You must add further information about the nature of the sequelae if ‘SAE status’ is ticked ‘resolved with sequelae’) |
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| **Study Medication / Intervention** | | | | Refer to code list C, D, E for below | | |
| **Study Drug / Intervention**  (List all study interventions and for study drugs indicate their route using code list B) | **Date of first administration**  dd/mm/yyyy | **Date of most recent administration**  dd/mm/yyyy | **Actual dose given at most recent administration with batch number** | **Causal**  **relationship to SAE** | **Expectedness\*\*(For related events only)** | **Action taken due to SAE** |
| Insert details |  |  |  |  |  |  |
| Insert details |  |  |  |  |  |  |
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| **Other treatments** (exclude therapies given for the treatment of the SAE, include concomitant medication, radiotherapy, surgery and palliative care, and rescue medication. Continue on separate sheet if necessary) | | | | | | **Indicate if not**   **applicable** | |
| **Treatment**  Give generic name | **Dose** (indicate if total dose, daily dose etc) | **Route** See code list B | **Start Date**  dd/mm/yyyy | **Ongoing**  Yes/No | **End Date**  dd/mm/yyyy | **Causal relationship to SAE**  See code list C | **Action taken due to SAE**  See code list E |
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| **Additional information** | | |
| Do you consider this event likely to have been caused by anything other than the treatment listed previously on this form? | No | Yes |
| If yes please specify: (for example medical history, family history, findings from special investigations, disease progression, co-morbidity) | | |
| Is there any further information you would like to add or outstanding results e.g. imaging or laboratory to forward, details of medication given for the SAE, reason for late reporting of SAE? | No | Yes |
| If yes, please specify: | | |

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| **Reporter’s signature:** | | | |  | | |
| Date: dd/mm/yyyy | | | | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  | / |  |  |  |  | | | |
| Printed name and position: | | | | | | |
| Phone and email contact details: | | | | | | |
| **Signature of medically qualified investigator who has assigned causality:** | | | |  | | |
| Date: dd/mm/yyyy | | | | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  | / |  |  |  |  | | | |
| Printed name and position: | | | | | | |
| Phone and email contact details: | | | | | | |
| Submit the signed SAE form to xxx@xxx **within 24 hours of site awareness**. Do not delay sending the form if all information is not available.  File the original in the Trial Master File or Investigator Site File, and ensure that the event is recorded in patient hospital notes and case report form where applicable. | | | | | | |
| **Coding** | | | | | | |
| A: SAE status | 1= Resolved | 2= Resolved with sequelae | 3= Ongoing | | 4= Fatal |  |
| B: Route | 1 = Oral | 2 = Intravenous | 3 = Subcutaneous | | 4 = Aerosolised | 5= Other, specify………….. |
| C: Causality | 0 = Unrelated | 1 = Related | Causality must be completed by a medically qualified investigator.  If protocol gives degrees of causality i.e. definitely, probably, etc., then update the coding table in this template in line with the protocol before use | | | |
| D: Expectedness | 1 = Expected | 2 = Unexpected | \*\*Insert instructions on how to conduct the expectedness assessment with where to find the expected events. For CTIMPs, expected events are listed in current approved reference safety information a section of the IB or SmPC. For non-CTIMPs, expected events would be listed in the protocol. | | | |
| E: Action | 0 = none | 1 = Dose reduced | 2 = Intervention delayed | | 3 = intervention reduced & delayed | 4 = intervention stopped |

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| **Unit / Coordinating Centre Office Use Only** |
| Coordinating Centre SAE Identifier: |
| Report received by: (print name and trial role / designation) |
| Is the event a SAE requiring immediate reporting in accordance with the protocol? (yes /no) |
| If yes to above, confirm date SAE report forwarded to \*\*insert protocol specified reviewer/review body: (DDMMYYYY) |