|  |  |
| --- | --- |
| **The form MUST be submitted within 24 hours of Trial team/Investigator becoming aware of the SAE**  **to tay.pharmacovigilance@nhs.scot, preferably as a PDF** | |
| * **Please check the protocol to ensure this is a reportable SAE** * **All section highlighted in BOLD must be completed before sending** | |
| * **Any additional information for follow-up reports should be added to the original submitted form** | |
| * **Causality and severity MUST be assessed by the Investigator or other delegated medically qualified doctor** | |
| **DO NOT INCLUDE:** | * **personal identifiable information (i.e. name, surname, CHI number)** |
| * **any supplementary information or documents unless requested** |

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| **1 – Report details** | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | |  | | | | | | | | | | | | | |  | | | |  | |
|  | | Initial Report | | | | | |  | | Follow Up Report | | | | | Country: | |  | | Centre ID: | | |  | | |  | |
|  | |  | | | | |  | | | | | | | | | | | | | |  | | | |  | |
| **2 – Subject details** | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | |  | | | | | | | | | | | | | |  | | | |  | |
|  | | | Initials: | |  | | | | Date of Birth: | | | | |  | | Sex: | | Male  Female | | | | | |  | | |
|  | |  | | | | |  | | | | | | | | | | | | | |  | | | |  | |
| **3 – SAE details** | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | |  | | | | | | | | | | | | | |  | | | |  | |
|  | |  | | **Is this a possible SUSAR? Yes**  **No**  *A Suspected Unexpected Serious Adverse Reaction (SUSAR) is a serious adverse reaction, the nature and severity of which is* ***not consistent*** *with the information about the medicinal product in question set out in the SmPC or IB* | | | | | | | | | | | | | | | | | | |  | |  | |
|  | |  | | | | |  | | | | | | | | | | | | | |  | | | |  | |
|  | | Onset date: | | | |  | | | | | | Diagnosis: |  | | | | | | | | | | | |  | |
|  | |  | | | | |  | | | | | | | | | | | | | |  | | | |  | |
|  | | | | | | | | | | | **Event narrative:** | | | | | | | | |  | | | | | | |
| *Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event not otherwise requested in this form* | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | **Seriousness criteria** *Tick all that apply* | | | | | | | | | |  | | |
|  |  |  | | | | | | | | | | | |  |  |
|  | Hospitalisation/Prolongation of hospitalisation | | | | | |  | Life-threatening | | | | | | |  |
|  |  | | | | | |  |  | | | | | | |  |
|  | Persistent/Significant Disability/Incapacity | | | | | |  | Other important medical event | | | | | | |  |
|  |  | | | | | |  |  | | | | | | |  |
|  | Congenital anomaly/Birth Defect | | | | | |  | Resulted in death¶*Complete section for fatal outcome* | | | | | | |  |
|  |  |  | | | | | | | | | | | |  |  |
|  | | | **Severity** | | | | | | | | |  | | | |
|  |  |  | | | | | | | | | | | |  |  |
|  | | | | Mild |  | Moderate | | |  | Severe |  | | | | |
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| **4 – Trial treatment** | | | | | | | | | | | | | | | | | | |
| *Please indicate the stage of the trial the participant was in (i.e. wash-out, run-in, on treatment)* | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | |  | | | | | |
| **Was the participant receiving trial IMP [any test drug including comparators] prior to the event?** | | | | | | | | | | | | | | | | Yes  No | |  |
| *If the trial is blinded please list all trial IMPs below* | | | | | | | | | | | | | | | |  | |  |
| Did the participant have to be unblinded? | | | | | | Yes  No  Not applicable | | | |  | | | | | | | | |
| If Yes, was the participant receiving placebo? | | | | | | Yes  No | |  | | | | | | | | | | |
|  | | | | **Trial IMPs** | | | | | | |  | | | | | | | |
|  | **Name of the IMP**  *Including comparators* | | **Dose** | | **Frequency** | **Route** | **Start date** | | **End date**  *Or tick if ongoing* | | | | |  | **Is the SAE causally related to IMP?** | | | |
| **1** |  | |  | |  |  |  | |  | | |  | |  | Yes  No | | *If YES,*  *please*  *complete section 5* | |
| **2** |  | |  | |  |  |  | |  | | |  | |  | Yes  No | |

*Please refill Page 2 separately if there are more than 2 trial IMPs (including comparators) or any NIMP (additional drugs required in the protocol)*

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| **5 – Causality assessment** \_*To complete* ***only*** *if SAE is causally related to IMP \_* | | | | | | | | | |
|  | | | | | | | | | |
| **Relationship to IMP 1:** | |  | Possible |  | Probable |  | Definite |  | |
|  | | | | | | | | | |
| **Relationship to IMP 2:** | |  | Possible |  | Probable |  | Definite |  | |
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| **6 – Action taken** | | | | | | |
|  | Dose not changed |  | Dose Increased |  | Not applicable |  |
|  | Drug withdrawn |  | Dose Reduced |  | Unknown |  |

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| **7 – Outcome** | | | | | | | | | | | | | | | |
|  | Recovered |  | Recovered with sequelae | | | | |  | Date of recovery: | | |  | |  | |
|  | Recovering |  | Not recovered | |  | | Unknown | | *Please send a follow-up report when information on recovery is available* | | | | | | |
|  | Fatal ¶ | Was the SAE the cause of death? | | | | | | | Yes  No | | *If No, please indicate the cause of death below* | | | | |
|  | Cause of death: | | |  | | | | | | | | | | |  |
|  | Date of death: | | |  | | Cause determined by Autopsy: | | | | Yes  No | | |  | |  |

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| **8 – Relevant medical history** | | | | | | |
| *Provide relevant medical history below*  *Include also other illnesses present at the time of the event, previous study emergent adverse events and pre-existing medical condition*  *If related medication was ongoing at the time of the event, this should be reflected in the Concomitant medications section below* | | | | | | |
| **Condition §** | **Start date** | **End date**  *or tick if ongoing* | |  | **Medication required** | |
|  |  |  |  |  | Yes | No |
|  |  |  |  |  | Yes | No |
|  |  |  |  |  | Yes | No |
|  |  |  |  |  | Yes | No |
|  |  |  |  |  | Yes | No |
|  |  |  |  |  | Yes | No |
|  |  |  |  |  | Yes | No |
|  |  |  |  |  | Yes | No |
|  |  |  |  |  | None | Possible |
|  |  |  |  |  | None | Possible |

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| **9 – Concomitant medications relevant to the event** | | | | | | | | | |
| *Please add any concomitant medication the participant was taking at the time of the SAE, not the medications used for its treatment* | | | | | | | | | |
| **Name of medication** | **Dose** | **Route** | **Frequency** | **Start date** | **End date**  *or tick if ongoing* | | **Indications** | **SAE causal relationship to medication** | |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |
|  |  |  |  |  |  |  |  | None | Possible |

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| **10 – Relevant tests** | | | | | |
| *Please list the confirmatory test results (i.e. from blood tests, diagnostic imaging) relevant to the diagnosis or the course of the SAE* | | | | | |
| **Test** | **Date** | **Normal range**  *Low-High* | **Units** | **Results** | **Comments** |
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| **11 – Re-challenge** | | | | | | |
| *Please complete if applicable, and if the SAE was related to the IMP, comparator or other concomitant medication* | | | | | | |
| Name of drug suspected to have caused the SAE: |  | | | | |  |
| Was the suspected drug stopped? | | No  Yes |  | Not applicable |  | |
| Did the reaction abate after stopping the suspected drug? | | No  Yes |  | Not applicable |  | |
| Did the reaction reappear after re-introduction of suspect drug? | | No  Yes |  | Not applicable |  | |

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| **Details of person completing this form** | | | |
| Title: |  | Designation/Role: |  |
| Name: |  | Organisation: |  |
| Email: |  | Department: |  |
| Tel: |  | Address: |  |
| City: |  | Postcode: |  |

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| **THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR** | |
| Name of Investigator | |
| Signature | Date |
| * Please send a signed and dated form within 24 hours to ***tay.pharmacovigilance@nhs.scot*** * A copy should also be added to your study site file * Receipt will be acknowledged by email | |