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| **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
 |