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# SERIOUS ADVERSE EVENT (SAE)/

# SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION (SUSAR) INITIAL REPORT FORM

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| **GUIDANCE FOR THE PERSON COMPLETING THIS FORM** |
| 1. Forms must be submitted to research@uhbw.nhs.uk in pdf format within 24 hours of the site research team becoming aware of the SAE. 2. Do not include personal identifiers (patient names, initials, dates of birth, CHI numbers, etc) on this form. 3. Complete the form as far as possible. The form can be updated/signed and re-submitted as new information becomes available. 4. Any updates should be added to the original form – DO NOTcreate a new form for each update to this SAE. 5. Please provide MedDRA term where possible. Your organisation should have access to the MedDRA code list (further information can be found here: <https://www.meddra.org/> 6. Further guidance can be found in UHBW WI\_002 Instructions and guidance for completion of Serious Adverse Event (SAE) forms: <https://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/templates-and-guidance/> |

1. **Study information**

**Study Title:**

**IRAS number:**

**Sponsor reference:**

**Current approved protocol version in use:**

**2. Details of participant affected by SAE/SUSAR**

**Sex at birth:**

**Participant ID:**

**Research site:**

**Age:**

**3. Details of event**

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| **Onset Date:**  (when event became serious) |  | **End date and time:** (if applicable) |  |
| **Event:**  This should be the diagnosis (or main symptom if diagnosis not known to be used as quick reference of event).  Multiple event names should not be used, please identify the *primary event* or report as separate SAEs if applicable. |  | | |
| **MedDRA preferred term:** |  | | |
| **Date investigator/research team became aware of event** |  | | |
| **Concise medical description of event/reaction, including body site and system, reported signs and symptoms (please specify the grade):** | | | |
|  | | | |
| **Seriousness criteria (tick all that apply):** | resulted in death  is/was life-threatening (at the time of the event, not hypothetically)  resulted in persistent or significant disability/incapacity  required hospitalisation (overnight admission)  prolonged an ongoing hospitalisation  resulted in a congenital anomaly or birth defect  other – please specify: | | |
| **Maximum severity of event:**  (up until time of initial report) | Mild Moderate Severe | | |

Sheet number:      of

**Complete Table 4 - if applicable**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **4. Details of IMP(s)/device/intervention(s)** | | | | | | | | | | | | | | | | |
| **Brand name** | **Indication** | | **Batch no.** | **Route**  (e.g. oral) | **Form**  (e.g. tablet) | | **Total dose/24h**  (specify units) | | | **Regimen** (e.g. BD) | | | **Start date**  & time | | **Stop date**  & time | **Suspected cause of SAE /SUSAR?** (Y/N) |
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| For blinded studies, was the randomisation code broken? | | | | | |  | | \*Yes |  | | No |  | | N/A | | |
| \*If yes, give details (by whom and when) | |  | | | | | | | | | | | | | | |

**Continue on new sheet if necessary; please identify how many sheets have been used.**

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| **5. Outcome** (*further space available in section 10)* | | | | | | |
| Outcome of event: | Resolved  Resolved with sequelae  Ongoing  Died (give cause and post-mortem details if available)  Unknown | | | | | |
| Further details regarding the outcome: |  | | | | | |
| Was the patient withdrawn from the study? | Yes  No | | | | | |
| **6. Action taken and further information** *(further space available in section 10)* | | | | | | |
| Please describe action taken (including details of IMP(s) where applicable e.g. drug withdrawn, clinical investigations, treatment received etc…): | | | | | | |
|  | | | | | | |
| Other information relevant to assessment of case e.g. medical history, family history, test results, concomitant medication: | | | | | | |
|  | | | | | | |
| **7. Causality Assessment – is the event related to the IMP(s)/device(s)/intervention:** | | | | | | |
| List IMP/device/intervention below  (add new rows as needed)  (For blinded studies all IMPs/devices/interventions should be listed and assessed for causality) | |  | | | | |
|  | | Not related | Unlikely to be related | Possibly related | Probably related | Definitely related |
|  | | Not related | Unlikely to be related | Possibly related | Probably related | Definitely related |
|  | | Not related | Unlikely to be related | Possibly related | Probably related | Definitely related |
| **Is this event expected of the IMP/device/study intervention**  **(note only required where ‘possibly, probably or definitely related’)** | | Expected  Unexpected | | | | |
| Name of person making causality, seriousness and expectedness assessment:  This must be a delegated medically qualified individual if a CTIMP or interventional surgical study, or device study | |  | | | | |
| Role in study: | |  | | | | |
| If not related to study IMP/device/intervention(s) what is the possible cause of the event? | |  | | | | |

Note: sponsor representative will assess expectedness of the event against the relevant Reference Safety Information and will inform site and CI if different to site expectedness assessment.

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| **8. Additional information (refer to section number)** | | | |
| Section no. | Further information | | |
|  |  | | |
| **9. Principal Investigator or delegated appropriately qualified individual\* (at this site)** | | | |
| **Name:**  (please print) | |  | |
| **Job title/role in study:** | |  | |
| **Email address:** | |  | |
| **Telephone No:** | |  | |
| **Signature:** | |  | **Date:** |
| I confirm that the contents of this form (pages 1, 2, 3, 4) are accurate and complete | | | |

\* This must be a medically qualified individual if a CTIMP, device trial or interventional surgical study

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| **10. Details of person completing this report (if different to PI/delegated other above)** | | |
| **Name:**  (please print) |  | |
| **Job title/role in study:** |  | |
| **Contact details:**  (email and telephone number) |  | |
| **Signature:** |  | **Date:** |
| I confirm that the contents of this form (pages 1, 2, 3, 4) are accurate and complete | | |

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| Please tick this box if additional pages have been used: |  |
| Number of additional pages used:(if applicable) |  |