Suspected Unexpected Serious Adverse Reaction Report (SUSAR) Form for Investigator-Led Trials

A privacy notice in relation to the personal data collected on this form is available on the HPRA website ([www.hpra.ie](http://www.hpra.ie)) under the ‘Report an Issue’ tab and by clicking on ‘Serious Adverse Event (Clinical Trials)’.

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| HPRA CT number:       HPRA reference no. (follow up reports only):       | Study protocol number:      CT authorised under:[ ]  Clinical Trials Regulation[ ]  Clinical Trials Directive |
| [ ]  Initial report[ ]  Follow up to the report of:       | Date of this report:       |

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| 1. PATIENT INFORMATION
 |
| Patient initials | Date of birth | Age | Sex | Weight | Is the patient pregnant? |
|       |       |       | [ ]  M [ ]  F |       | [ ]  Yes [ ]  No |

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| 1. DESCRIPTION OF THE SUSAR
 |
| Category of SUSAR *(tick all that apply)*: [ ]  Patient died [ ]  Life threatening [ ]  Required or prolonged in-patient hospitalisation[ ]  Involved persistent or significant disability[ ]  Medically significant[ ]  Congenital anomaly/birth defect |
| Description of SUSAR: *signs and symptoms, diagnosis, course, include relevant lab data and details of treatment administered. (Additional information may be provided on a separate page.)*      |

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| 1. INFORMATION ABOUT THE SUSAR
 |
| Start date | Stop date/ ongoing | Relationship to study drug | Study drug action | Recovery status |
|       |       | [ ]  Not related[ ]  Possible[ ]  Probable[ ]  Definite | [ ]  Permanently discontinued[ ]  Temporarily discontinued[ ]  Dose reduction | [ ]  Recovered without sequelae[ ]  Recovered with sequelae[ ]  Unknown[ ]  Not yet recovered[ ]  Fatal |

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| 1. Suspect Drug Information
 |
| Suspect drug | INN | Indication | Daily dose | Route | Start date | Stop date |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |

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| 1. Relationship to Study Medication
 |
| Did the SUSAR abate upon discontinuation of study medication?[ ]  Yes[ ]  No[ ]  N/A | Did the SUSAR recur upon the reintroduction of study medication?[ ]  Yes[ ]  No[ ]  N/A |

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| 1. Concomitant medication
 |
| Brand name | INN | Indication | Daily dose | Route | Start date | Stop date |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |
| Please tick if no concomitant medications were administered: [ ]   |

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| 1. Other RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last menstrual period date, etc.)
 |
| Description | Start date | End date |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

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| 1. Reporter Information
 |
| Name (signature) | Name (block capitals) | Date | Title | Telephone no. |
|       |       |       |       |       |

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| 1. Investigator
 |
| Name (signature) | Name (block capitals) | Date | Was this event |
|       |       |       | [ ]  Expected[ ]  Unexpected |

Send to:

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