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 |
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| 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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