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| **Independent Ethics Committee** | Serious Adverse Event (SAE) Report *Please submit this form with a cover letter* |

All serious adverse events (whether they are expected or unexpected, causally related or unrelated) occurring in the investigator’s research site (i.e. sites that are approved by IEC SJMC) are to be reported to IEC by the Investigator or his research team using this form.

a) For fatal / life-threatening SUSARS: report to IEC (cc investigator) within 7 calendar days from first knowledge by the Investigator. Additional information should be submitted within 8 calendar days.

b) For non-fatal / life-threatening SUSARS: report to IEC within 15 calendar days from first knowledge by the Investigator.

EXTERNAL sites SUSARs (i.e. multicentre trials, where events happen at other institution either in Malaysia or foreign) are to be submitted to IEC as individual reports AND as line listing at regular intervals.

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| **Title of research project** |  |
| Research protocol number / NMRR ID | / |
| Principal investigator’s Name |  |
| Research site | Subang Jaya Medical Centre  Others: |
| Name of sponsor |  |

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| **Type of SAE report** (Tick one) | New/initial  Follow up  Final Report | | |
| Subject Initials |  | | |
| Age |  | Sex | Male  Female |
| Relevant Medical History |  | | |
| Date of SAE onset |  | Date of SAE resolution |  |
| Date when SAE was *first* informed to investigator or research team |  | | |
| Description of SAE |  | | |
| SAE Classification | Resulted in death  Is life-threatening  Requires inpatient hospitalization or prolongation of existing hospitalization  Results in persistent or significant disability/incapacity  Is a congenital anomaly/birth defect  Other (Important medical events) | | |

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| **Information on suspected drug(s)** | | | | |
| Name of drug(s) |  | | Dose |  |
| Route of administration |  | | Indication |  |
| Treatment dates | From (start date) |  | To (end date/ongoing) |  |
| Concomitant drug(s)  (Provide name, route of administration and dose) |  | | | |

**Assessment of causality by investigator**

Do you consider this SAE to have a causal relationship to the suspected drug? (Tick below)

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| Definitely Related | Where a temporal (timely) relationship of the onset of the event, relative to the administration of the product is reasonable and there is no other cause to explain the event (or a rechallenge is positive) e.g. bone marrow depression following administration of cytotoxic chemotherapy. |
| Probably Related | Where a temporal (timely) relationship of the onset of the event, relative to the administration of the product is reasonable and the event is more likely to be explained by the medicinal product than by another cause e.g. nausea and vomiting. |
| Possibly Related | Where a temporal (timely) relationship of the onset of the event, relative to the administration of the product is reasonable, but the event could have been due to an equally likely cause e.g. headache. |
| Unlikely to be Related | Where a temporal (timely) relationship of the onset of the event, relative to the administration of the product is unlikely but cannot be ruled out e.g. mouth ulcer following administration of an oral drug. |
| Not Related | Where a temporal (timely) relationship of the onset of the event, relative to the administration of the product is not reasonable e.g. cut finger. Or where another cause can explain the occurrence of the event by itself e.g. headache associated with migraine. |

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| What were the measures taken? | Suspected drug discontinued  Dose reduced  Drug treatment for the SAE  No drug treatment given for the SAE  Discontinuation of concomitant drug(s)  Non-drug treatment (specify) |

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| **Comments by Investigator**  Does this SAE significantly alter the risk-benefit analysis to the research subjects in this research project? | |
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| Name of reporter |  |
| Signature of reporter |  |
| Date of report |  |

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| Please send this completed report along with a softcopy submission to: | The Secretariat, Independent Ethics Committee, c/o Clinical Trial Office. 1st Floor, South Tower, Subang Jaya Medical Centre, No 1, SS12/1A, 47500 Subang Jaya.  Soft copy should be emailed [sjmc.iec@asia1health.com](mailto:rsdh.iec@asia1health.com)  Should you require further clarification, please do not hesitate to contact The Secretariat at  03- 5639 1988 / 1989 |