SERIOUS ADVERSE EVENT

Protocol No: ________________________________

In-house study: Patient’s Number: PW ☐ ☐ ☐

Industry study: Patient’s Number: ________________________

If the event meets the definition of serious adverse event, complete these SAE pages. If not, complete a Non-serious AE page.

All bold and italic columns must be completed for the initial report.

1. ☐ Initial report Date : ☐ ☐-☐ ☐-☐ ☐ ☐-☐ ☐-☐ ☐
   (Report within 24 hrs of learning of SAE)
☐ Follow-up report Date : ☐ ☐-☐ ☐-☐ ☐ ☐-☐ ☐-☐ ☐
   (Report when case completed)

2. Patient Information: Patient Initials: ☐ ☐ ☐
   Date of Birth: ☐ ☐-☐ ☐-☐ ☐ ☐ ☐
   Sex: ☐ (1=Male 2=Female)
   Latest Body Weight: ☐ ☐ ☐.☐ kg
   Height: ☐ ☐ ☐.☐ cm

3. Date of onset (admission date): ☐ ☐-☐ ☐-☐ ☐ ☐-☐ ☐-☐ ☐
   Severity (toxicity grading): ☐ (1, 2, 3, 4, 5)
   1. Grade 1 - mild  2. Grade 2 - moderate  3. Grade 3 - severe
   4. Grade 4 - life-threatening or disabling  5. Fatal
   Event (NCI CTC Code): ______________________________
   1. Record only one event that meets one or more of the SAE criteria.
   2. Complete unique CTC code of the SAE event. Please refer to the CTC booklet.
   3. Study nurse must also complete the AE CRF.

4. Narrative Description of Adverse Event:
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________
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5. Adverse Event Classification (check all appropriate):
(    )  Death                                                                (    )  Congenital Anomaly
(    )  Life Threatening                                                (    )  New Cancer
(    ) Required or Prolonged Hospitalization             (    ) Overdose
(    ) Severe or Permanently Disabling                      (    ) Other (specify):

6. Outcome at the time of initial report:

1. Not available           3. Resolved
2. Ongoing                    4. Died

7. Date of resolution or death (if applicable) Please complete the additional comment on follow up report

8. Study Medication(s): (exclude concomitant medications)

<table>
<thead>
<tr>
<th>Name</th>
<th>Date of last dose (DD-MM-YYYY)</th>
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9. Action taken with trial medication as a result of the SAE:

1. None
2. Dosage adjusted
3. Temporarily interrupted
4. Permanently discontinued

Withdrawal from study as a result of the SAE:

1. No
2. Yes

Relationship to trial medication:

1. Unrelated
2. Unlikely*
3. Possible*
4. Probable*
5. Definite*

*Unlikely (doubtfully related)  Possible (may be related)  Probable (likely related)  Definite (clearly related)
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10. Additional Comment on follow up report: (Include treatments/procedures for SAE)

_______________________________________________________________________
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If necessary, continue the follow up report in additional sheet.

Investigator/CO investigator to certify that he/she has carefully examined the SAE form and all information recorded in the form is accurate

(Initial Report)

PI’s printed name: ___________________________ Date: ☐ ☐ ☐ ☐ mm yyyy

PI’s Signature: ____________________________

(Follow up Report)

PI’s printed name: ___________________________ Date: ☐ ☐ ☐ ☐ mm yyyy

PI’s Signature: ____________________________

For Office Use only:

SAE follow up form completed on: Date ☐ ☐ ☐ ☐ mm yyyy

1. Send the copy of initial report/follow-up report within 15 working days to EC of Chinese University for all studies
2. Send electronic initial report/follow-up report within 15 working days to EC of Cancer Trials for Industry studies
3. File the SAE form in SAE report file when completed