

SERIOUS ADVERSE EVENT (SAE) REPORT FORM

Page 1-2 to be transmitted to *[insert name]* within 24 hours of knowledge of SAE.

| | | | |
|---------------------------------|-------------|--|---------------------|
| Site No.: | Patient ID: | Initial Report: <input type="checkbox"/> | Follow up Report #: |
| Principal Investigator: | | | |
| Institution (name and address): | | | |
| Protocol Code: | | SAE No. | |
| SAE Description: | | | |

PATIENT DETAILS

Gender M F

DATE OF BIRTH (dd/mm/yy) |_|_|/|_|_|/|_|_|

SERIOUS ADVERSE EVENT INFORMATION

Onset Date: |_|_|/|_|_|/|_|_| (dd/mm/yy)

Adverse Event In Medical Terms (INITIAL DEFINITION): _____

MedDRA Code (Version __. __)

System Organ Class (SOC) _____

High Level Group Term _____

Lowest Level Term _____

Preferred Term _____

Seriousness Criteria (check all appropriate to event)

- life-threatening
- death
- involved or prolonged hospitalization
- disability
- congenital anomaly/birth defect
- important medical event (e.g., intervention required to prevent one of the above)

Date of worsening _____

Expectedness Expected Unexpected

Outcome (check only one)

- resolved
- resolved with sequelae
- unresolved / ongoing
- death
- unknown / lost to follow-up

Resolution Date (or death date if SAE outcome is death):

|_|_|/|_|_|/|_|_| (DD/MM/YY)

| IMP(S) INFORMATION (SUSPECTED RELATED DRUG) | | | |
|---|---|--|--|
| IMP(s) | Date / Time of Last IMP Dose Before the Event | IMP Start / Stop (dd/mm/yy) | IMP Relationship Assessment (for each IMP): <u><IMP NAME></u> |
| Name _____ Batch _____ Route/ Schedule _____ | Date: _ _ / _ _ / _ _ Time: _____ : _____ (if SAE onset on same day) Cycle# _____ Day# _____ | First Dose: _ _ / _ _ / _ _ Last Dose: _ _ / _ _ / _ _ or Ongoing <input type="checkbox"/> | UNRELATED <input type="checkbox"/> UNLIKELY <input type="checkbox"/> POSSIBLE <input type="checkbox"/> PROBABLE <input type="checkbox"/> DEFINITE <input type="checkbox"/> |

| OTHER RELEVANT ADVERSE EVENT INFORMATION |
|---|
| <p>Action taken for each IMP (check all appropriate to event):</p> <p><input type="checkbox"/> NO CHANGE</p> <p><input type="checkbox"/> <u><IMP NAME></u> Dosage Adjusted / Temporarily Interrupted *</p> <p><input type="checkbox"/> <u><IMP NAME></u> Permanently discontinued due to SAE *</p> <p style="text-align: right;">* if ticked, provide relevant details in section 9.</p> |
| <p>Corrective therapy:</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Drug-therapy given*</p> <p><input type="checkbox"/> NON- Drug-therapy given*</p> <p style="text-align: right;">* if ticked, provide relevant details in section 9.</p> |
| <p>Did the Adverse Event abate after stopping, interrupting, or reducing the dose of the study drug(s)?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable</p> |
| <p>Did the Adverse Event reoccur after reintroducing the study drug(s)?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable</p> |

| Maximum severity grade (CTCAE V) | Hospitalization details (if applicable) | Death details (complete if patient died due to the reported SAE or due to another cause while SAE was ongoing and provide details in Section 9.) |
|--|---|---|
| Grade I <input type="checkbox"/> Grade II <input type="checkbox"/> Grade III <input type="checkbox"/> Grade IV <input type="checkbox"/> Grade V <input type="checkbox"/> | <input type="checkbox"/> New hospitalization <input type="checkbox"/> Prolongation of hospitalization Admission date: _ _ / _ _ / _ _ Discharge date: _ _ / _ _ / _ _ | Date of death: _ _ / _ _ / _ _ Primary cause(s) of death: <hr/> Autopsy performed: <input type="checkbox"/> YES <input type="checkbox"/> NO (if yes, please attach report) |

| CONCOMITANT DRUGS RELEVANT TO THE SAE (exclude therapy to treat SAE) | | | | | |
|--|-------|----------|------------|------------|------------|
| Drug Name | Dose | Unit | Start Date | Stop Date | Indication |
| | Route | Schedule | (dd/mm/yy) | (dd/mm/yy) | |
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SUSPECT CONCOMITANT DRUG (If SAE is considered to have a possible causal relationship with any of the above-mentioned concomitant medications, please comment)

TESTS / LABORATORY FINDINGS

(enter only those findings necessary for SAE diagnosis or course description.)

If copy of source documents or CRF attached, please circle or underline relevant values and sign each page)

| Test | Date (Dd/Mm/Yy) | Value /Unit | Date (Dd/Mm/Yy) | Value /Unit | Lower Normal Value | Upper Nomal Value |
|------|--------------------|----------------|--------------------|-------------|-----------------------|----------------------|
| | | | | | | |
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PATIENT'S RELEVANT MEDICAL HISTORY

(e.g. concurrent medical conditions such as disease, allergies, similar experiences)

SAE NARRATIVE AND ADDITIONAL INFORMATION

(Provide a detailed description of the SAE including related signs/symptoms, treatment, course/outcome and suspected cause of the SAE)

Person reporting SAE: _____

Investigator Signature: _____

Date: |_|_|/|_|_|/|_|_|