

3. Action taken for participant

- ☐ Withdrawal from the trial due to SAE?
- ☐ Other actions taken (e.g. surgery, drug treatment for SAE, etc.)?

[free text]

4. SAE seriousness

- ☐ Results in death
- ☐ Is life-threatening
- ☐ Requires inpatient hospitalisation or prolongation of existing hospitalisation

Date of admission: [day/month/year]

Date of discharge: [day/month/year] ☐ ongoing

- ☐ Results in persistent or significant disability/incapacity or
- ☐ Is a congenital anomaly/birth defect

If applicable, other criteria according to ICH E2A/protocol: [free text] _____

- ☐ Other medically important event: [free text] _____

5. Evaluation of the SAE

Intensity of symptoms

Grading scale used: [instruction to Sponsor-Investigator: Please prefill the grading scale used in the study before sending the SAE reporting template to the sites]

Grade:

Outcome (tick one)

- ☐ Recovered/resolved ☐ Ongoing
- ☐ Recovered/resolved with sequelae ☐ Unknown
- Specify sequelae:
- ☐ Fatal
- ☐ Other [free text]
- ☐ Not resolved at death (independent of the SAE)

In case of death:

Autopsy performed: ☐ yes ☐ no

Cause of death (if autopsy is yes): [free text]

Date of death: [day/month/year]

Autopsy report available: ☐ yes ☐ no

6. IMP(s) information and evaluation

- ☐ Double blind * ☐ Open label ☐ Other:

*If Double Blind Phase, Randomization Number :

*Was the blinding broken? ☐ No ☐ Yes, date: [day/month/year] Reason for breaking the blind:

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ML Yell



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