

PELICAN SAE instruction

The SAE reporting procedure is the same for both study arms.

SAE definitions

A SAE is defined as[#]: any untoward medical occurrence or effect that at any dose:

- is life-threatening or fatal;
- requires or prolongs hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect;
- is considered an important medical event*.

* Important medical events are those which may not be immediately life-threatening, but are clearly of major clinical significance. They may jeopardise the patient, and may require intervention to prevent one of the other serious outcomes.

[#] For a SAE occurring due to progression of disease reporting is not required in the PELICAN trial.

Reporting procedure for Serious adverse events

Information about SAEs that occur within 28 days after last day of protocol treatment is collected and recorded on the Serious Adverse Event Report Form. The local investigator will determine if the events are related to the study treatment (i.e. unrelated, unlikely, possible, probable, definitely and not assessable). The SAE form should be completed in the English language and should be send within 24 hours from moment of first knowledge.

The SAE Form should be send by email within 24 hours after the initial observation of the event to the **IKNL Clinical research department; e-mail: trialbureau@iknl.nl**

For questions or remarks please email or phone +31 (0)88-2346500. The IKNL clinical research department is responsible for reporting the SAE to the authorities. All SAEs will be reported in the annual safety report.

Follow up & final

A follow-up report is expected within two weeks after the initial report, and the final report should be submitted within two weeks after the stop date. The follow up and final report should be updated versions of the initial report.

All forms should be dated and signed by the responsible investigator or one of his/hers staff members*

*please note that any staff member completing or signing the SAE form should be noted on the delegation log.