Serious Adverse Event (SAE) Report

(To be filled by the principal investigator)

Principal investigator: .....
Protocol No: .....

Study Title:
.....
.....

Study Period: .....

Name of the studied medicine/device: .....

Study site: ……..

Sponsor (if any) :.....

No.	Description of unexpected adverse event	Date of Event	Date start and end of treatment	sex	Age	Seriousness (Y/N)	Related to study (Y/N)	Concomitant medication	Intervention	Remarks

Causality statement:

Statement on whether adverse event necessitates an amendment to the project and/or the patient information sheet/consent form:

Any other comments :