**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) :.........................................................

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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  |
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Causality statement:

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

Any other comments :