Adverse Event

Was the event serious?
1. Resulted in Death
2. Life-threatening
3. Requiring inpatient hospitalisation or prolongation of existing hospitalisation
4. Persistent or significant disability/incapacity
5. Congenital anomaly/birth defect

Was the SAE specified in the protocol as exempt from reporting on the SAE form? e.g.

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Causal relationship to protocol medication?
- Definitely
- Probably
- Possibly
- Unlikely
- Not related

Was the SAE one of the recognised undesirable effects of the trial medication specified in the IB, SPC (appendix N)

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CRF: Case Report Form
IB: Investigators brochure
SAE: Serious adverse event
SAR: Serious adverse reaction
SPC: Summary of product characteristics
SUSAR: Suspected unexpected serious adverse reaction