

**SERIOUS ADVERSE EVENTS OF SPECIAL INTEREST**

**SAEs of special interest are events that:**

- result in death
- are life threatening (at the time of the event)
- are a primary or secondary endpoint
- are (potentially) related to study procedures
- occur during or within 1 week of hospital admission for the index event or staged PCI.
- are cardiac in nature

**Subject number:** .....**Age:** .....**Gender:** Male/Female**Start date of the event:** .././....**End date of the event:** .././....**Relationship of the SAE to (study) procedures**

- Unexpected outcome of an expected serious complication
- An SAE related to a study procedure
- An SAE related to a medical device
- An SAE related to failure of equipment
- Other,.....

**SAE category:**

- It resulted in death
- It was life threatening (at the time of the event)
- It required hospitalization or prolongation of the existing hospitalization
- The patient has a congenital disorder
- It resulted in persistent or significant disability or incapacity
- Other

**Outcome:**

- Recovered
- Recovering
- Not recovered
- Recovered with sequelae
- Fatal
- Unknown

**Provide a description of the event**

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**Other relevant information (e.g. test results)**

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**Please add anonymized supporting documentation of the event to this worksheet and send it to [Robin.Nijveldt@radboudumc.nl](mailto:Robin.Nijveldt@radboudumc.nl) and [Yvonne.Koop@radboudumc.nl](mailto:Yvonne.Koop@radboudumc.nl), thank you!**