

Study number:

Date of inclusion: \_\_\_/\_\_\_/\_\_\_

**(SERIOUS) ADVERSE EVENTS ((S)AE) CRF**

**(S)AE number: 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10**

**General information**

Initials investigator: \_\_\_\_\_

Signature investigator: \_\_\_\_\_

Date of report: \_\_\_/\_\_\_/\_\_\_

Date of (S)AE onset \_\_\_/\_\_\_/\_\_\_

**Description of (S)AE (in Dutch or English):**

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**Deterioration and neuro-imaging**

Neurologic deterioration of 4 points or more on NIHSS:  Yes  No

Neurologic deterioration of 2 points or more on 1 NIHSS subcategory:  Yes  No

Was there neuro-imaging performed for this (S)AE:  Yes  No

Was this event an adverse event or a serious adverse event:  AE (continue to relationship with study procedures)  SAE

**Serious Adverse Event category, please choose one:**

- Results in death
- Life threatening (at the time of event)
- Requires prolonged hospitalization
- Results in persistent or significant disability or incapacity
- Other, please specify: \_\_\_\_\_
- Not listed above (i.e. not a **serious** adverse event)

**SAE expected?**

*An SAE is 'expected' if this is one of the known side effects of the study treatment or one of the common (potentially) serious complications after stroke.*

No  Yes

**Select most likely cause of SAE, please choose one:**

- Stroke progression
- New ischemic stroke, which territory \_\_\_\_\_
- Intracranial hemorrhage
- Extracranial hemorrhage
- Cardiac Ischemia
- Allergic reaction
- Pneumonia
- Other infection, \_\_\_\_\_
- Other, \_\_\_\_\_

**Was there another cause for SAE, you may choose multiple**

No  Yes

- Stroke progression
- New ischemic stroke
- Intracranial hemorrhage
- Extracranial hemorrhage
- Cardiac Ischemia
- Allergic reaction
- Pneumonia
- Other infection, \_\_\_\_\_
- Other, \_\_\_\_\_

**Relationship with the study procedures:**

- None
- Unlikely
- Possible
- Probable
- Definite

**Actions regarding study participation**

- None
- Interrupted
- Stopped
- Other, please specify: \_\_\_\_\_

**Outcome**

- Resolved without sequelae date: \_\_\_/\_\_\_/\_\_\_
- Resolved with sequela(e) date: \_\_\_/\_\_\_/\_\_\_ and describe sequela(e): \_\_\_\_\_
- Ongoing (pending) \_\_\_\_\_
- Death date: \_\_\_/\_\_\_/\_\_\_



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**Review all Data for this Visit**

Physician

Date: \_\_\_/\_\_\_/\_\_\_

Signature: \_\_\_\_\_

Study Nurse

Date: \_\_\_/\_\_\_/\_\_\_

Signature: \_\_\_\_\_

Other, comments: \_\_\_\_\_

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