Study number: _____ Date of inclusion: ____/____/_____

Patient sticker/label

OR

Patient name: _____ +

Patient ID: _____

SERIOUS ADVERSE EVENT (SAE) CRF

General information

Name investigator: _____ Signature investigator:

Date of report: ____/____/_____ DD/MM/YYYY

Description of SAE (in Dutch or English):

_____

_____

_____

_____

_____

_____

_____

_____

Date of SAE onset

Date: ____/____/_____ DD/MM/YYYY

Neurological deterioration and/or neuroimaging

Neurological deterioration of 4 points or more on NIHSS?	□ No	□ Yes
Neurological deterioration of 2 points or more on **one NIHSS Item**?	□ No	□ Yes
Was there neuroimaging performed for this SAE/Neurological deterioration?	□ No	□ Yes

Serious Adverse Event **category**, please choose one:	SAE **expected**?
□ **0** – Results in death □ **1** – Life threatening (at the time of event) □ **2** – Requires or prolongs hospitalisation □ **3** – Results in persistent or significant disability or incapacity □ **4** – Other, please specify: _____	*An SAE is 'expected' if this is one of the known side effects of the study medication or one of the common (potentially) serious complications after stroke as listed in appendices 8 and 9 of the study protocol.* ***If No: please report the unexpected SAE within 24 hours to mrasap@amc.nl*** □ No □ Yes
Select **most likely cause of** SAE, please choose one:	Was there **another cause** of (S)AE, you may choose multiple
□ **0** – Stroke progression □ **1** – New ischaemic stroke: □ Same □ Different vascular territory □ **2** – Intracranial haemorrhage □ **3** – Extracranial haemorrhage □ **4** – Cardiac ischaemia □ **5** – Allergic reaction □ **6** – Pneumonia □ **7** – Other infection, please specify: _____ □ **8** – Hypotension requiring clinical intervention □ **9** – Hypertension requiring clinical intervention □ **10** – Other, please specify: _____	□ No □ Yes: □ **0** – Stroke progression □ **1** – New ischaemic stroke: □ Same □ Different vascular territory □ **2** – Intracranial haemorrhage □ **3** – Extracranial haemorrhage □ **4** – Cardiac ischaemia □ **5** – Allergic reaction □ **6** – Pneumonia □ **7** – Other infection: _____ □ **8** – Hypotension requiring clinical intervention □ **9** – Hypertension requiring clinical intervention □ **10** – Other, please specify:_____
Relationship with the study treatment	**Actions** regarding the study treatment:
□ **0** – None □ **1** – Unlikely □ **2** – Possible □ **3** – Probable □ **4** – Definite	□ **0** – None □ **1** – Interrupted □ **2** – Discontinued □ **3** – Other, please specify: _____

Outcome

□ **0** – Resolved without sequela(e)	date: __ /__ /____ DD/MM/YYYY
□ **1** – Resolved with sequela(e)	date: __ /__ /____ DD/MM/YYYY and describe sequela(e): _____
□ **2** – Ongoing (pending)	_____
□ **3** – Death	date: __ /__ /____ DD/MM/YYYY

Additional SAE forms are available on the website: https://mrasap.nl/documents.html