

Study number:

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

**CLINICAL FOLLOW UP CRF**

**24 hours follow-up**

**Vital parameters at 1, 6, 12 and 24 hours**

<b>Vital parameters at 1 hour after arrival in ER neurosurgical center:</b>		<i>Round numbers</i>
Systolic blood pressure _____ mm Hg	Diastolic blood pressure _____ mm Hg	
Heart rate _____ /min		

<b>Vital parameters at 6 hours:</b>		<i>Round numbers</i>
Systolic blood pressure _____ mm Hg	Diastolic blood pressure _____ mm Hg	
Heart rate _____ /min		

<b>Vital parameters at 12 hours:</b>		<i>Round numbers</i>
Systolic blood pressure _____ mm Hg	Diastolic blood pressure _____ mm Hg	
Heart rate _____ /min		

<b>Vital parameters at 24 hours:</b>		<i>Round numbers</i>
Systolic blood pressure _____ mm Hg	Diastolic blood pressure _____ mm Hg	
Heart rate _____ /min		

**Treatment limitations at 24 hours**

**Any combination of these strategies is possible**

Did the treatment limitations at 24 hours change compared to baseline?	<input type="checkbox"/> No <input type="checkbox"/> Yes: <b>if Yes, please fill out below</b>
Do-not-resuscitate	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding endotracheal intubation	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding intensive care admission	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding other treatments that may prolong life	<input type="checkbox"/> No <input type="checkbox"/> Yes <i>(e.g. antibiotics, blood transfusion)</i>
Withholding food and fluids	<input type="checkbox"/> No <input type="checkbox"/> Yes
Palliation with morphine	<input type="checkbox"/> No <input type="checkbox"/> Yes
Palliation with benzodiazepine	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withdrawal of care	<input type="checkbox"/> No <input type="checkbox"/> Yes <i>(discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)</i>

Location of the patient at 24 hours	<input type="checkbox"/> 0 - ICU <input type="checkbox"/> 1 - Medium care <input type="checkbox"/> 2 - Stroke Unit <input type="checkbox"/> 3 - General ward
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**Neuroimaging at 24 hours (±6 hours)**

Did you perform a non-contrast CT-scan at 24 hours?	<input type="checkbox"/> No <input type="checkbox"/> Yes
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**(S)AE Check at 24 hours**

Did the patient experience one or more (serious) adverse event(s)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <b>(if Yes, please complete (S)AE form(s))</b>
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**Day 3 ( $\pm 12$  hours) follow-up (DIST-INFLAME sub-study only)**

**Inclusion in the DIST-INFLAME sub-study**

Is the patient included in the DIST-INFLAME sub-study?  No  Yes: **if Yes, please fill in information below**

**Vital parameters at day 3 ( $\pm 12$  hours)**

Date of examination: \_\_\_/\_\_\_/\_\_\_

**Vital parameters at day 3:**

*Round numbers*

Systolic blood pressure \_\_\_\_\_ mm Hg

Diastolic blood pressure \_\_\_\_\_ mm Hg

Heart rate \_\_\_\_\_ /min

**DIST-INFLAME sub-study blood sample at day 3 ( $\pm 12$  hours)**

Did you take a DIST-INFLAME sub-study blood sample at day 3?  No  Yes

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**Day 6 ± 1 day follow-up (or discharge, if earlier)**

**Vital parameters at day 6 ± 1 day**

Date of examination: \_\_\_/\_\_\_/\_\_\_

Vital parameters at 6 ± 1 days (or discharge if earlier):		Round numbers
Systolic blood pressure _____ mm Hg	Diastolic blood pressure _____ mm Hg	
Heart rate _____ /min		

**NIHSS at day 6 ± 1 day (or discharge if earlier)**

Date of examination: \_\_\_/\_\_\_/\_\_\_

<b>1A Level of consciousness (LOC)</b> <input type="checkbox"/> 0 – Alert <input type="checkbox"/> 1 – Not alert, but arousable <input type="checkbox"/> 2 – Not alert, requires repeated stimulation <input type="checkbox"/> 3 – Comatose	<b>1B LOC Questions</b> <input type="checkbox"/> 0 – Answers both questions correctly <input type="checkbox"/> 1 – Answers one question correctly <input type="checkbox"/> 2 – Answers neither questions correctly
<b>1C LOC Commands</b> <input type="checkbox"/> 0 – Performs both tasks correctly <input type="checkbox"/> 1 – Performs one task correctly <input type="checkbox"/> 2 – Performs neither tasks correctly	<b>2 Best gaze</b> <input type="checkbox"/> 0 – Normal <input type="checkbox"/> 1 – Partial gaze palsy <input type="checkbox"/> 2 – Forced deviation
<b>3 Visual</b> <input type="checkbox"/> 0 – No visual loss <input type="checkbox"/> 1 – Partial hemianopia <input type="checkbox"/> 2 – Complete hemianopia <input type="checkbox"/> 3 – Bilateral hemianopia	<b>4 Facial palsy</b> <input type="checkbox"/> 0 – Normal <input type="checkbox"/> 1 – Minor paralysis <input type="checkbox"/> 2 – Partial paralysis <input type="checkbox"/> 3 – Complete paralysis
<b>5A Motor left arm</b> <input type="checkbox"/> 0 – No drift <input type="checkbox"/> 1 – Drift <input type="checkbox"/> 2 – Some effort against gravity <input type="checkbox"/> 3 – No effort against gravity <input type="checkbox"/> 4 – No movement <input type="checkbox"/> 9 – Untestable, explain reason: _____	<b>5B Motor right arm</b> <input type="checkbox"/> 0 – No drift <input type="checkbox"/> 1 – Drift <input type="checkbox"/> 2 – Some effort against gravity <input type="checkbox"/> 3 – No effort against gravity <input type="checkbox"/> 4 – No movement <input type="checkbox"/> 9 – Untestable, explain reason: _____
<b>6A Motor left leg</b> <input type="checkbox"/> 0 – No drift <input type="checkbox"/> 1 – Drift <input type="checkbox"/> 2 – Some effort against gravity <input type="checkbox"/> 3 – No effort against gravity <input type="checkbox"/> 4 – No movement <input type="checkbox"/> 9 – Untestable, explain reason: _____	<b>6B Motor right leg</b> <input type="checkbox"/> 0 – No drift <input type="checkbox"/> 1 – Drift <input type="checkbox"/> 2 – Some effort against gravity <input type="checkbox"/> 3 – No effort against gravity <input type="checkbox"/> 4 – No movement <input type="checkbox"/> 9 – Untestable, explain reason: _____
<b>7 Limb ataxia</b> <input type="checkbox"/> 0 – Absent <input type="checkbox"/> 1 – Present in one limb <input type="checkbox"/> 2 – Present in two limbs <input type="checkbox"/> 9 – Untestable, explain reason: _____	<b>8 Sensory</b> <input type="checkbox"/> 0 – Normal <input type="checkbox"/> 1 – Mild to moderate sensory loss <input type="checkbox"/> 2 – Severe or total sensory loss
<b>9 Best language</b> <input type="checkbox"/> 0 – No aphasia (normal) <input type="checkbox"/> 1 – Mild to moderate aphasia <input type="checkbox"/> 2 – Severe aphasia <input type="checkbox"/> 3 – Mute, global aphasia	<b>10 Dysarthria</b> <input type="checkbox"/> 0 – Normal <input type="checkbox"/> 1 – Mild to moderate dysarthria <input type="checkbox"/> 2 – Severe dysarthria, anarthria, mute <input type="checkbox"/> 9 – Intubated, or other, explain: _____
<b>11 Extinction and inattention</b> <input type="checkbox"/> 0 – No abnormality <input type="checkbox"/> 1 – Inattention or extinction to one sensory modality <input type="checkbox"/> 2 – Profound hemi-inattention or extinction to more than one modality	(modalities: visual/tactile/auditory/spatial/personal)



Study number:

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

**EQ-5D-5L at day 6 ± 1 day (or discharge if earlier)**

Date of examination: \_\_\_/\_\_\_/\_\_\_

<b>1. Mobility</b> <input type="checkbox"/> 1 – I have no problems in walking about <input type="checkbox"/> 2 – I have slight problems in walking about <input type="checkbox"/> 3 – I have moderate problems in walking about <input type="checkbox"/> 4 – I have severe problems in walking about <input type="checkbox"/> 5 – I am unable to walk about	<b>2. Self-care</b> <input type="checkbox"/> 1 – I have no problems washing or dressing myself <input type="checkbox"/> 2 – I have slight problems washing or dressing myself <input type="checkbox"/> 3 – I have moderate problems washing or dressing myself <input type="checkbox"/> 4 – I have severe problems washing or dressing myself <input type="checkbox"/> 5 – I am unable to wash and dress myself
<b>3. Usual activities</b> <input type="checkbox"/> 1 – I have no problems doing my usual activities <input type="checkbox"/> 2 – I have slight problems doing my usual activities <input type="checkbox"/> 3 – I have moderate problems doing my usual activities <input type="checkbox"/> 4 – I have severe problems doing my usual activities <input type="checkbox"/> 5 – I am unable to do my usual activities	<b>4. Pain/discomfort</b> <input type="checkbox"/> 1 – I have no pain or discomfort <input type="checkbox"/> 2 – I have slight pain or discomfort <input type="checkbox"/> 3 – I have moderate pain or discomfort <input type="checkbox"/> 4 – I have severe pain or discomfort <input type="checkbox"/> 5 – I have extreme pain or discomfort
<b>5. Anxiety/depression</b> <input type="checkbox"/> 1 – I am not anxious or depressed <input type="checkbox"/> 2 – I am slightly anxious or depressed <input type="checkbox"/> 3 – I am moderately anxious or depressed <input type="checkbox"/> 4 – I am severely anxious or depressed <input type="checkbox"/> 5 – I am extremely anxious or depressed	<b>EQ-VAS</b> Reported health today (0-100): _____
<b>EQ-5D-5L completed by</b>	<input type="checkbox"/> patient <input type="checkbox"/> proxy

**Treatment limitations at day 6 ± 1 day (or discharge if earlier)**

Date of assessment: \_\_\_/\_\_\_/\_\_\_

<b>Any combination of these strategies is possible</b>	
Did the treatment limitations at day 6 ± 1 day change compared to 24 hours?	<input type="checkbox"/> No <input type="checkbox"/> Yes: <b>if Yes, please fill out below</b>
Do-not-resuscitate	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding endotracheal intubation	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding intensive care admission	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withholding other treatments that may prolong life	<input type="checkbox"/> No <input type="checkbox"/> Yes (e.g. antibiotics, blood transfusion)
Withholding food and fluids	<input type="checkbox"/> No <input type="checkbox"/> Yes
Palliation with morphine	<input type="checkbox"/> No <input type="checkbox"/> Yes
Palliation with benzodiazepine	<input type="checkbox"/> No <input type="checkbox"/> Yes
Withdrawal of care	<input type="checkbox"/> No <input type="checkbox"/> Yes (discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)
Location of the patient at day 6 ± 1 day	<input type="checkbox"/> 0 - ICU <input type="checkbox"/> 1 - Medium care <input type="checkbox"/> 2 - Stroke Unit <input type="checkbox"/> 3 - General ward

**Neuroimaging at day 6 ± 1 day (or discharge if earlier)**

Did you perform a non-contrast CT-scan at day 6 ± 1 day (or discharge if earlier)?	<input type="checkbox"/> No <input type="checkbox"/> Yes
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**DIST-INFLAME sub-study blood sample at day 6 ± 1 day (or discharge if earlier)**

Did you take a DIST-INFLAME sub-study blood sample at day 6 ± 1 day? (DIST-INFLAME sub-study only)	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> NA
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**(S)AE Check at day 6 ± 1 day (or discharge if earlier)**

Did the patient experience one or more (serious) adverse event(s)?	<input type="checkbox"/> No <input type="checkbox"/> Yes (if Yes, please complete (S)AE form(s))
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## Discharge – Neurosurgical center

### Neuroimaging

Any additional neuroimaging performed during hospital stay? (excluding study neuroimaging)  No  Yes

### Interventions and diagnoses during hospital stay

Neurological deterioration (NIHSS  $\geq 4$ ) due to ICH expansion  No  Yes: **fill out SAE form**

Intracranial infection  No  Yes: **fill out SAE form**

Seizure(s)  No  Yes: **fill out SAE form**

Intubation (excluding intubation for study surgery)  No  Yes: **fill out SAE form**

Surgical intervention (excluding study surgery)  No  Yes: **fill out SAE form**

If yes, specify:

External ventricular drain (EVD)  No  Yes Date of intervention: \_\_\_/\_\_\_/\_\_\_

Craniotomy with hematoma evacuation  No  Yes Date of intervention: \_\_\_/\_\_\_/\_\_\_

Hemicraniectomy with hematoma evacuation  No  Yes Date of intervention: \_\_\_/\_\_\_/\_\_\_

Hemicraniectomy without hematoma evacuation  No  Yes Date of intervention: \_\_\_/\_\_\_/\_\_\_

ICP monitoring  No  Yes Date of intervention: \_\_\_/\_\_\_/\_\_\_

Burr hole(s)  No  Yes Date of intervention: \_\_\_/\_\_\_/\_\_\_

Other: \_\_\_\_\_ Date of intervention: \_\_\_/\_\_\_/\_\_\_

Other major medical intervention  No  Yes: **fill out SAE form and describe:** \_\_\_\_\_

### Antihypertensive medication during hospital stay

Any type of antihypertensive medication  No  Yes:

			<i>If applicable:</i>
Intravenous labetalol	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Intravenous nicardipine	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
ACE inhibitor	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Angiotensin II receptor antagonist	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Beta blocker	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Calcium channel blocker	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Diuretic	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Other (intravenous or oral): _____		Start date ___/___/___	Stop date ___/___/___

### Platelet inhibitor(s) during hospital stay

Any type of platelet inhibitor  No  Yes:

			<i>If applicable:</i>
Acetylsalicylic acid/carbasalate calcium	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Clopidogrel	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Dipyridamole	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Ticagrelor	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Other: _____		Start date ___/___/___	Stop date ___/___/___

### Direct oral anticoagulant (DOAC) during hospital stay

Any type of DOAC  No  Yes:

			<i>If applicable:</i>
Apixaban (Eliquis®)	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Dabigatran (Pradaxa®)	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Edoxaban (Lixiana®)	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Rivaroxaban (Xarelto®)	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___

### Vitamin K antagonist(s) during hospital stay

Any type of vitamin K antagonist  No  Yes:

			<i>If applicable:</i>
Acenocoumarol	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Phenprocoumon	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___

### Heparin during hospital stay

Any type of heparin  No  Yes:

			<i>If applicable:</i>
Prophylactic heparin	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___
Therapeutic heparin	<input type="checkbox"/> No <input type="checkbox"/> Yes	Start date ___/___/___	Stop date ___/___/___

### Admission

Was the patient admitted to the:

- ICU  No  Yes  
 - Medium care  No  Yes  
 - Stroke Unit  No  Yes  
 - General ward (not stroke unit)  No  Yes

Total number of days in:

- ICU \_\_\_\_\_  
 - Medium care \_\_\_\_\_  
 - Stroke Unit \_\_\_\_\_  
 - General ward \_\_\_\_\_

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### Discharge

Was the patient discharged  No  Yes  
Date of discharge (dead or alive) \_\_\_/\_\_\_/\_\_\_

Discharge destination:  
 **0** - Patient died (**please fill out SAE form**)  
 **1** - Home  
 **2** - Other hospital (**transfer; please fill out transfer CRF**)  
 **3** - Geriatric rehabilitation  
 **4** - Nursing home long stay  
 **5** - Rehabilitation center  
 **6** - Other: \_\_\_\_\_

Name of discharge destination: \_\_\_\_\_

### Treatment limitations at discharge – Neurosurgical center

#### Any combination of these strategies is possible

Did the treatment limitations at discharge change compared to day 6 ± 1 day?  No  Yes: **if Yes, please fill out below**

- Do-not-resuscitate  No  Yes
- Withholding endotracheal intubation  No  Yes
- Withholding intensive care admission  No  Yes
- Withholding other treatments that may prolong life  No  Yes *(e.g. antibiotics, blood transfusion)*
- Withholding food and fluids  No  Yes
- Palliation with morphine  No  Yes
- Palliation with benzodiazepine  No  Yes
- Withdrawal of care  No  Yes *(discontinuation of life-prolonging treatments, e.g. mechanical ventilation, vasopressor medications)*

### (S)AE Check at discharge – Neurosurgical center

Did the patient experience one or more (serious) adverse event(s) during hospital stay?  No  Yes (**if Yes, please complete (S)AE form(s)**)