MRCLEAN - REGISTRY

CRF ON PAPER

Version 13.0 CJC/MK/RJG/DD/CM
February 2018

Study number: …….

Inclusion date: ____ /____ /_____

Data entry date: ____ /____ /_____ Signature: _____

INSTRUCTIE:

Wij vragen u het formulier zo volledig mogelijk in te vullen. Zeer belangrijk is het tevens invullen van de gegevens in de digitale MR CLEAN-Registry database, bereikbaar via www.MRCLEAN-trial.org. De papieren versie is een werkdocument en kan lokaal bewaard worden.

Wij danken u voor medewerking aan de MR CLEAN Registry.

Met vriendelijke groet,

MR CLEAN-Registry Trial Office

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BASELINE

Inclusion criteria MR CLEAN-Registry			
1. Clinical diagnosis of acute stroke	☐ No ☐ Yes	4. Patient treated with intra-arterial therapy	☐ No ☐ Yes
2. Intracranial arterial occlusion of the distal intracranial carotid artery, anterior (A1/A2), middle (M1/M2) cerebral artery or posterior cerebral artery (VA/BA/P1) (demonstrated with CTA, MRA, DSA)	☐ No ☐ Yes	5. Are all above criteria met? **If not, please still include patient in MR CLEAN Registry but do not follow up**	☐ No ☐ Yes
3. Retrospective informed consent given	☐ No ☐ Yes		

Timing of baseline procedures	**(missing code = 9999)**		
Time of 1: ☐ last seen well or 2: ☐ onset	_____ hh:mm	Time start of alteplase (if given)	_____ hh:mm
Inhospital patient? ☐ No ☐ Yes		Contra-indications for alteplase	☐ No ☐ Yes
Transfer from other hospital? ☐ No ☐ Yes Name: _____		If yes, please specify: _____	
Time arrival ER (first hospital)	_____ hh:mm		
Time plain CT-baseline (first hospital)	_____ hh:mm	**Metrics**	
Time CTA-baseline (first hospital)	_____ hh:mm	Body temperature	_____ degrees Celsius
Time arrival ER (intervention hospital)	_____ hh:mm	Weight	_____ kg Height _____ cm
Time plain CT-baseline (intervention hospital)	_____ hh:mm	Systolic BP	_____ mm Hg
Time CTA-baseline (intervention hospital)	_____ hh:mm	Diastolic BP	_____ mm Hg

History

Previous Ischemic stroke	☐ No ☐ Yes ☐ Unk	Peripheral artery disease	☐ No ☐ Yes ☐ Unk	Antiplatelet use	☐ No ☐ Yes ☐ Unk
If yes, in same arterial distribution as current stroke?	☐ No ☐ Yes ☐ Unk	Diabetes Mellitus	☐ No ☐ Yes ☐ Unk	Use of new oral anticoagulants (NOA's)	☐ No ☐ Yes ☐ Unk
Intra-cranial hemorrhage	☐ No ☐ Yes ☐ Unk	Atrial fibrillation	☐ No ☐ Yes ☐ Unk	Use of heparin(oid)	☐ No ☐ Yes ☐ Unk
Severe head injury	☐ No ☐ Yes ☐ Unk	Hypercholesterolemia	☐ No ☐ Yes ☐ Unk	Use of antihypertensive drugs	☐ No ☐ Yes ☐ Unk
Myocardial infarction	☐ No ☐ Yes ☐ Unk	Smoking	☐ No ☐ Yes ☐ Unk	Use of statins	☐ No ☐ Yes ☐ Unk
Hypertension	☐ No ☐ Yes ☐ Unk			Use of coumarines	☐ No ☐ Yes ☐ Unk

Glasgow Coma Score	**Motor**	**Verbal**
Eye	☐ 6 Obeys commands	☐ 5 Oriented/converses normally
☐ 4 Opens eyes spontaneously	☐ 5 Localizes painful stimuli	☐ 4 Confused/disoriented
☐ 3 Opens eyes in response to voice	☐ 4 Flexion/withdrawal to painful stimuli	☐ 3 Utters inappropriate words
☐ 2 Open eyes after painful stimuli	☐ 3 Abnormal flexion to painful stimuli	☐ 2 Incomprehensible sounds
☐ 1 Does not open eyes	☐ 2 Extension to painful stimuli	☐ 1 No sounds
	☐ 1 No movements	

Pre-stroke mRS	**Lab Information**	**(missing code = 9999)**
☐ 0 No symptoms	INR	_____
☐ 1 Minor symptoms, no limitations	Thrombocyte count	_____ x10^9/L
☐ 2 Slight disability, no help needed	Serum Creatinine	_____ umol/L
☐ 3 Moderate disability, still independent	CRP	_____ mg/L
☐ 4 Moderately severe disability	Serum Glucose	_____ mmol/L
☐ 5 Severe disability, completely dependent	Comorbidity influencing mRS? ☐ No ☐ Yes, please specify: _____	

Imaging modality	**Performed**	**Sent to AMC**		
Non-contrast CT	☐ No ☐ Yes	☐ Yes ☐ Not applicable	Date of scan _____ /_____ /_____ (dd/mm/yyyy)	
			Performed in:	☐ Referring hospital → please specify: _____ ☐ Intervention hospital ☐ Both → please specify referring hospital: - _____
CTA	☐ No ☐ Yes	☐ Yes ☐ Not applicable	Performed in:	☐ Referring hospital → please specify: _____ ☐ Intervention hospital ☐ Both → please specify referring hospital: _____
CT-Perfusion	☐ No ☐ Yes	☐ Yes ☐ Not applicable		
MR (DWI)	☐ No ☐ Yes	☐ Yes ☐ Not applicable		
MRA	☐ No ☐ Yes	☐ Yes ☐ Not applicable		

SERIOUS ADVERSE EVENTS (SAE) CHECK

Did the patient experience a serious adverse event in this episode? ☐ No ☐ Yes **(if yes, please complete SAE-form on final page)**

NIH STROKE SCALE (NIHSS)

Please fill out the NIHSS twice: at baseline and after 24-48 hours. For each item, an additional explanation is given on the next page.

Study number: .....

Inclusion date: _____ / _____ / _____ (dd-mm-yyyy)

	BASELINE	24-48 HOURS
	Date:	**Date:**
	Time:	**Time:**
	Physician:	**Physician:**

Item:		Description:	Score:	Score:
1a	Level of consciousness.	0 = alert. 1 = not alert, but arousable by minor stimulation to obey, answer, or respond. 2 = not alert, requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped). 3 = coma (unresponsive).		
1b	LOC questions.	0 = answers both questions correctly. 1 = answers one question correctly. 2 = answers neither question correctly.		
1c	LOC commands.	0 = performs both tasks correctly. 1= performs one task correctly. 2 = performs neither tasks correctly.		
2	Gaze.	0 = normal 1 = partial gaze palsy. This score is given when gaze is abnormal in one or both eyes, but where forced deviation or total gaze paresis are not present. 2 = forced deviation, or total gaze paresis not overcome by the oculocephalic maneuver.		
3	Visual.	0 = no visual loss. 1 = partial hemianopia. 2 = complete hemianopia. 3 = bilateral hemianopia (blind, including cortical blindness)		
4	Facial palsy.	0 = normaal/symmetrical. 1 = minor paralysis (flattened nasolabial fold, asymmetry on smiling) 2 = partial paralysis (total or near total paralysis of lower face) 3 = complete paralysis of one or both sides (absence of facial movement in the upper and lower face)		
5a	Motor function. • Left arm.	0 = no drift, limb holds 90° for full 10 seconds. 1 = drift, Limb holds 90° , but drifts down before full 10 seconds 2 = some effort against gravity, limb cannot get to or maintain 90 3 = no effort against gravity, limb falls. 4 = no movement 9 = untestable (e.g. amputation); elaborate:.....		
5b	Motor function. • Right arm.	0 = no drift, limb holds 90° for full 10 seconds. 1 = drift, Limb holds 90° , but drifts down before full 10 seconds 2 = some effort against gravity, limb cannot get to or maintain 90 3 = no effort against gravity, limb falls. 4 = no movement 9 = untestable (e.g. amputation); elaborate:.....		
6a	Motor function • Left leg	0 = no drift, leg holds 30° position for full 5 seconds. 1 = drift, leg falls by the end of the 5 second period . 2 = some effort against gravity; leg falls to bed by 5 seconds. 3 = no effort against gravity, leg falls to bed immediately. 4 = no movement. 9 = untestable (e.g. amputation); elaborate:.....		
6b	Motor function. • Right leg.	0 = no drift, leg holds 30° position for full 5 seconds. 1 = drift, leg falls by the end of the 5 second period . 2 = some effort against gravity; leg falls to bed by 5 seconds. 3 = no effort against gravity, leg falls to bed immediately. 4 = no movement. 9 = untestable (e.g. amputation); elaborate:.....		
7	Limb ataxia.	0 = absent. 1 = present in one limb. 2 = present in two limbs.		
8	Sensory.	0 = normal. 1 = mild to moderate sensory loss. 2 = severe to total sensory loss.		
9	Language.	0 = no aphasia 1 = mild tot moderate aphasia. 2 = severe aphasia. 3 = mute, global aphasia; no usable speech or auditory comprehension.		
10	Dysarthria.	0 = normal articulation 1 = mild to moderate; patient can be understood with some difficulty. 2 = Severe; patient's speech is unintelligible in the absence of or out of proportion to any dysphasia, or is mute. 9 = Intubated or other physical barrier; elaborate:		
11	Extinction and inattention.	0 = no abnormality 1 = visual, tactile, auditory, spatial, or personal inattention or extinction. 2 = profound hemi-inattention or hemi-inattention to more than one modality..		
		Total score:		

1a. Level of Consciousness: the investigator must choose a response, even if a full evaluation is prevented by such obstacles as an endotracheal tube, language barrier, orotracheal trauma/bandages. A 3 is scored only if the patient makes no movement (other than reflexive posturing) in response to noxious stimulation.

1b. LOC Questions: the patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, language barrier or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues.

1c. LOC Commands: the patient is asked to open and close the eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task should be demonstrated to them (pantomime) and score the result (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored.

2. Gaze: only horizontal eye movements will be tested. Voluntary or reflexive (oculocephalic) eye movements will be scored but caloric testing is not done. If the patient has a conjugate deviation of the eyes that can be overcome by voluntary or reflexive activity, the score will be 1. If a patient has an isolated peripheral nerve paresis (CN III, IV or VI) score a 1. Gaze is testable in all aphasic patients. Patients with ocular trauma, bandages, pre-existing blindness or other disorder of visual acuity or fields should be tested with reflexive movements and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of a partial gaze palsy.

3. Visual: visual fields (upper and lower quadrants) are tested by confrontation, using finger counting or visual threat as appropriate. Patient must be encouraged, but if they look at the side of the moving fingers appropriately, this can be scored as normal. If there is unilateral blindness or enucleation, visual fields in the remaining eye are scored. Score 1 only if a clear-cut asymmetry, including quadrantanopia is found. If patient is blind from any cause score 3. Double simultaneous stimulation is performed at this point. If there is extinction patient receives a 1 and the results are used to answer question 11.

4. Facial palsy: ask, or use pantomime to encourage the patient to show teeth or raise eyebrows and close eyes. Score symmetry of grimace in response to noxious stimuli in the poorly responsive or non-comprehending patient. If facial trauma/bandages, orotracheal tube, tape or other physical barrier obscures the face, these should be removed to the extent possible.

5 & 6. Motor function arm and Leg: the limb is placed in the appropriate position: extend the arms (palms down) 90 degrees (if sitting) or 45 degrees (if supine) and the leg 30 degrees (always tested supine). Drift is scored if the arm falls before 10 seconds or the leg before 5 seconds. The aphasic patient is encouraged using urgency in the voice and pantomime but not noxious stimulation. Each limb is tested in turn, beginning with the non-paretic arm. Only in the case of amputation or joint fusion at the shoulder or hip may the score be "9" and the examiner must clearly write the explanation for scoring as a "9".

7. Limb Ataxia: this item is aimed at finding evidence of a unilateral cerebellar lesion. Test with eyes open. In case of visual defect, insure testing is done in intact visual field. The finger-nose-finger and heel-shin tests are performed on both sides, and ataxia is scored only if present out of proportion to weakness. Ataxia is absent in the patient who cannot understand or is paralyzed. Only in the case of amputation or joint fusion may the item be scored "9", and the examiner must clearly write the explanation for not scoring. In case of blindness test by touching nose from extended arm position.

8. Sensory: sensation or grimace to pin prick when tested, or withdrawal from noxious stimulus in the obtunded or aphasic patient. Only sensory loss attributed to stroke is scored as abnormal and the examiner should test as many body areas [arms (not hands), legs, trunk, face] as needed to accurately check for hemisensory loss. A score of 2, "severe or total," should only be given when a severe or total loss of sensation can be clearly demonstrated. Stuporous and aphasic patients will therefore probably score 1 or 0. The patient with brain stem stroke who has bilateral loss of sensation is scored 2. If the patient does not respond and is quadriplegic score 2. Patients in coma (item 1a = 3) are arbitrarily given a 2 on this item.

9. Best language: a great deal of information about comprehension will be obtained during the preceding sections of the examination. The patient is asked to describe what is happening in the attached picture, to name the items on the attached naming sheet, and to read from the attached list of sentences. Comprehension is judged from responses here as well as to all of the commands in the preceding general neurological exam. If visual loss interferes with the tests, ask the patient to identify objects placed in the hand, repeat, and produce speech. The intubated patient should be asked to write. The patient in coma (question 1a=3) will arbitrarily score 3 on this item. The examiner must choose a score in the patient with stupor or limited cooperation but a score of 3 should be used only if the patient is mute and follows no one step commands.

10. Dysarthria: if patient is thought to be normal an adequate sample of speech must be obtained by asking patient to read or repeat words from the attached list. If the patient has severe aphasia, the clarity of articulation of spontaneous speech can be rated. Only if the patient is intubated or has other physical barrier to producing speech, may the item be scored "9", and the examiner must clearly write an explanation for not scoring. Do not tell the patient why he/she is being tested.

11. Extinction and inattention (formerly 'Neglect'): sufficient information to identify neglect may be obtained during the prior testing. If the patient has a severe visual loss preventing visual double simultaneous stimulation, and the cutaneous stimuli are normal, the score is normal. If the patient has aphasia but does appear to attend to both sides, the score is normal. The presence of visual spatial neglect or anosagnosia may also be taken as evidence of abnormality. Since the abnormality is scored only if present, the item is never untestable.

SERIOUS ADVERSE EVENTS (SAE) CHECK

Did the patient experience a serious adverse event in this episode? ☐ No ☐ Yes **(if yes, please complete SAE-form on final page)**

MRCLEAN-R: INTERVENTION

CASE REGISTRATION FORM

Date: ___ / ___ / _____ (dd/mm/yyyy)

1st interventionalist: .....

2nd interventionalist: .....

3rd interventionalist: .....

Paste patient sticker or write down:
Name:
Gender:
Patient #:
Birth date:

1. Intervention

□ Catheterization only
□ DSA only
□ Intervention

If no intervention is performed, please explain:
.....
.....

2. eTICI-score before intra-arterial treatment:

□ 0: No perfusion or antegrade flow beyond site of occlusion
□ 1: Penetration but not perfusion. Contrast penetration exists past the initial obstruction but with minimal filling of the normal territory
□ 2A: Some perfusion with distal branch filling of <50% of territory vascularized
□ 2B: Substantial perfusion with distal branch filling of ≥50% of territory visualized
□ 2C: Near-complete perfusion except for slow flow in a few distal cortical vessels or presence of small distal cortical emboli
□ 3: Complete perfusion with normal filling of all distal branches

3. Location of occlusion:

□ M1 □ M2 □ A1 □ A2 □ ICA □ ICA-T □ VA □ BA □ P1 □ other: .....
Side: □ Left □ Right

4a. General anesthesia during procedure: □ no □ yes
4b. Conscious sedation during procedure: □ no □ yes

5. Medication administered during procedure:

□ heparin Total dose: ..... IU
□ abciximab (Reopro) Total dose: ..... mg
□ other ..... Total dose: .....

6. Treatment with mechanical device:

□ Guiding catheter: □ 6F □ 8F Balloon: □ no □ yes

□ Stent-retriever:
□ Solitaire attempts: .....
□ Revive attempts: .....
□ Catch attempts: .....
□ TREVO attempts: .....
□ Other:..... attempts: .....

□ Aspiration device: ..... attempts: .....

□ MERCI-retriever attempts: .....

□ Other: ..... attempts: .....

Please specify which stent was used first: .....

ATTENTION: TURN OVER! Please fill out backside as well!

7. Treatment with **intra-arterial** thrombolytic: □ no □ urokinase, dose: …… □ alteplase, dose:……

8. Time

- Arrival patient in angio-suite: …….. (hh:mm)
- Groin puncture: ……..
- First attempt with device: ……..
- Time of first recanlization (TICI 2b/3) or last contrast bolus: ……..
- Sheath from groin: ……..
- Total duration of IA treatment (groin puncture to sheath withdrawal) …….. minutes

9. Thrombus extracted for PA: □ no □ yes

10. eTICI-score after intra-arterial treatment:

- □ 0: No perfusion
- □ 1: Antegrade reperfusion past the initial occlusion, but limited distal branch filling with little or slow distal reperfusion
- □ 2A: Antegrade reperfusion of less than half of the occluded target artery previously ischemic territory (e.g. in 1 major division of the MCA and its territory)
- □ 2B: Antegrade reperfusion of more than half of the previously occluded target artery ischemic territory (e.g. in 2 major divisions of the MCA and their territories)
- □ 2C: Near-complete perfusion except for slow in a few distal cortical vessels or presence of small distal cortical emboli
- □ 3: Complete antegrade reperfusion of the previously occluded target artery ischemic territory, with absence of visualized occlusion in all branches

11. Procedural complications / adverse events (e.g. vasospasm, dissection, perforation or peripheral emboli):

12. Description of procedure (optional):

13. Closure device used:

□ angioseal
□ other, please specify type: ……
Side: □ Left □ Right

14. Have all images been transferred to the PACS system?
Please include baseline & post-intervention AP + lateral imaging up until venous phase.

15. Signature: _____ Date: ___ / ___ / _____ (dd/mm/yyyy)

Post-intervention IMAGING

Performed? ☐ **No** ☐ **Yes**

If YES, please fill in below:

IMAGING #1

Date of scan _____ /_____ / _____ **(dd/mm/yyyy)**				**Sent to AMC:** ☐ Yes ☐ Not applicable			
Modality	Non-contrast CT	☐ No	☐ Yes	MRA	☐ No	☐ Yes	Other: _____
	CTA	☐ No	☐ Yes	MR (DWI)	☐ No	☐ Yes	
Hemorrhage	☐ No ☐ Yes						
Hemorrhagic transformation	☐ No ☐ Yes						

IMAGING #2

Date of scan _____ /_____ / _____ **(dd/mm/yyyy)**				**Sent to AMC:** ☐ Yes ☐ Not applicable			
Modality	Non-contrast CT	☐ No	☐ Yes	MRA	☐ No	☐ Yes	Other: _____
	CTA	☐ No	☐ Yes	MR (DWI)	☐ No	☐ Yes	
Hemorrhage	☐ No ☐ Yes						
Hemorrhagic transformation	☐ No ☐ Yes						

IMAGING #3

Date of scan _____ /_____ / _____ **(dd/mm/yyyy)**				**Sent to AMC:** ☐ Yes ☐ Not applicable			
Modality	Non-contrast CT	☐ No	☐ Yes	MRA	☐ No	☐ Yes	Other: _____
	CTA	☐ No	☐ Yes	MR (DWI)	☐ No	☐ Yes	
Hemorrhage	☐ No ☐ Yes						
Hemorrhagic transformation	☐ No ☐ Yes						

ADMISSION TO ICU / MC / STROKE UNIT

Was the patient admitted to ICU	☐ No ☐ Yes	Total number of days in ICU	_____
Was the patient admitted to High Care	☐ No ☐ Yes	Total number of days in High Care	_____
Was the patient admitted to stroke unit	☐ No ☐ Yes	Total number of days in stroke unit	_____

DISCHARGE

Discharge date from endovascular treatment hospital or **date of death:** _____ /_____ / _____ **(dd/mm/yyyy)**

Discharge destination

☐ Own home

☐ Nursing home, name & city: _____

☐ Hospital, name & city: _____

☐ Rehabilitation center, name & city: _____

☐ Other, name & city: _____

SERIOUS ADVERSE EVENTS (SAE) CHECK

Did the patient experience a serious adverse event in this episode? ☐ No ☐ Yes **(if yes, please complete SAE-form on final page)**

3 MONTH FOLLOW UP

Date ____ /_____ /_____

Questions answered by: ☐ Patient ☐ Other, _____

Patient information

Patient residential status

☐ Own home

☐ Nursing home, name: _____

☐ Hospital, name: _____

☐ Rehabilitation center, name: _____

Number of readmissions to hospital _____ Hospital name(s): 1. _____ 2. _____

Reason: _____

Admission planned before stroke event? ☐ No ☐ Yes

3 month mRS

☐ 0 No symptoms

☐ 1 Minor symptoms, no limitations

☐ 2 Slight disability, no help needed

☐ 3 Moderate disability, still independent

☐ 4 Moderately severe disability

☐ 5 Severe disability, completely dependent

☐ 6 Death, date of death: _____ / _____ / _____ (dd / mm / yyyy)

Remarks:

_____

_____

_____

_____

Comorbidity influencing mRS? ☐ No ☐ Yes, please specify:

_____

_____

_____

_____

_____

_____

SERIOUS ADVERSE EVENTS (SAE) FORM 1

Study number: _____

Date of SAE onset: _____

Date of SAE resolution: _____

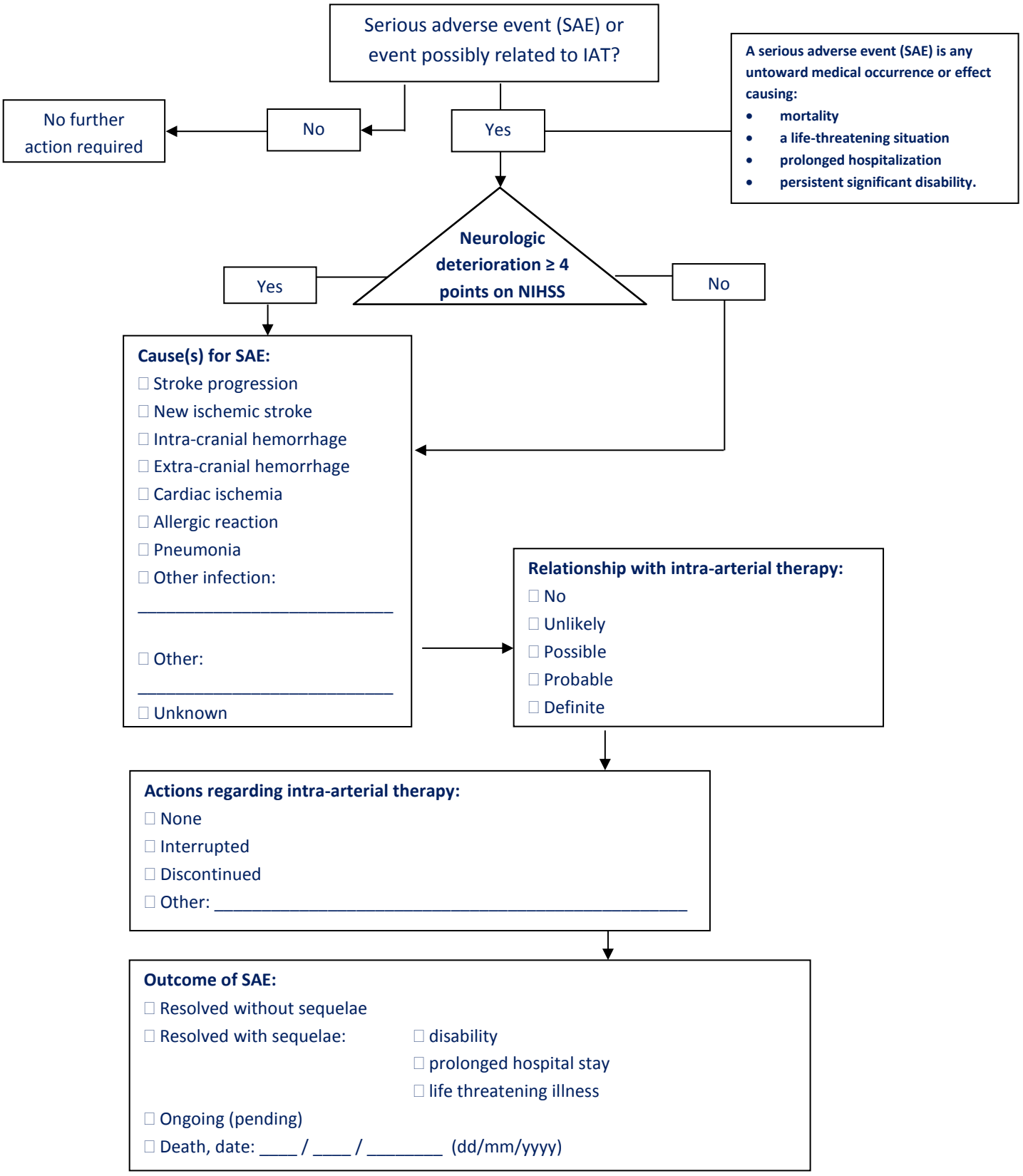
Physician name: _____

Physician signature: _____

Date of SAE registration: _____ / _____ / _____
(dd / mm / yyyy)

Phase of occurence:
- ☐ Baseline
- ☐ Peri-interventional
- ☐ Within 24 hours
- ☐ Between 24 hours and 48 hours
- ☐ Between 48 hours and discharge
- ☐ Between discharge and 3 month follow up

Please fill out the SAE flow chart:



SERIOUS ADVERSE EVENTS (SAE) FORM 2

Study number: _____

Date of SAE onset: _____

Date of SAE resolution: _____

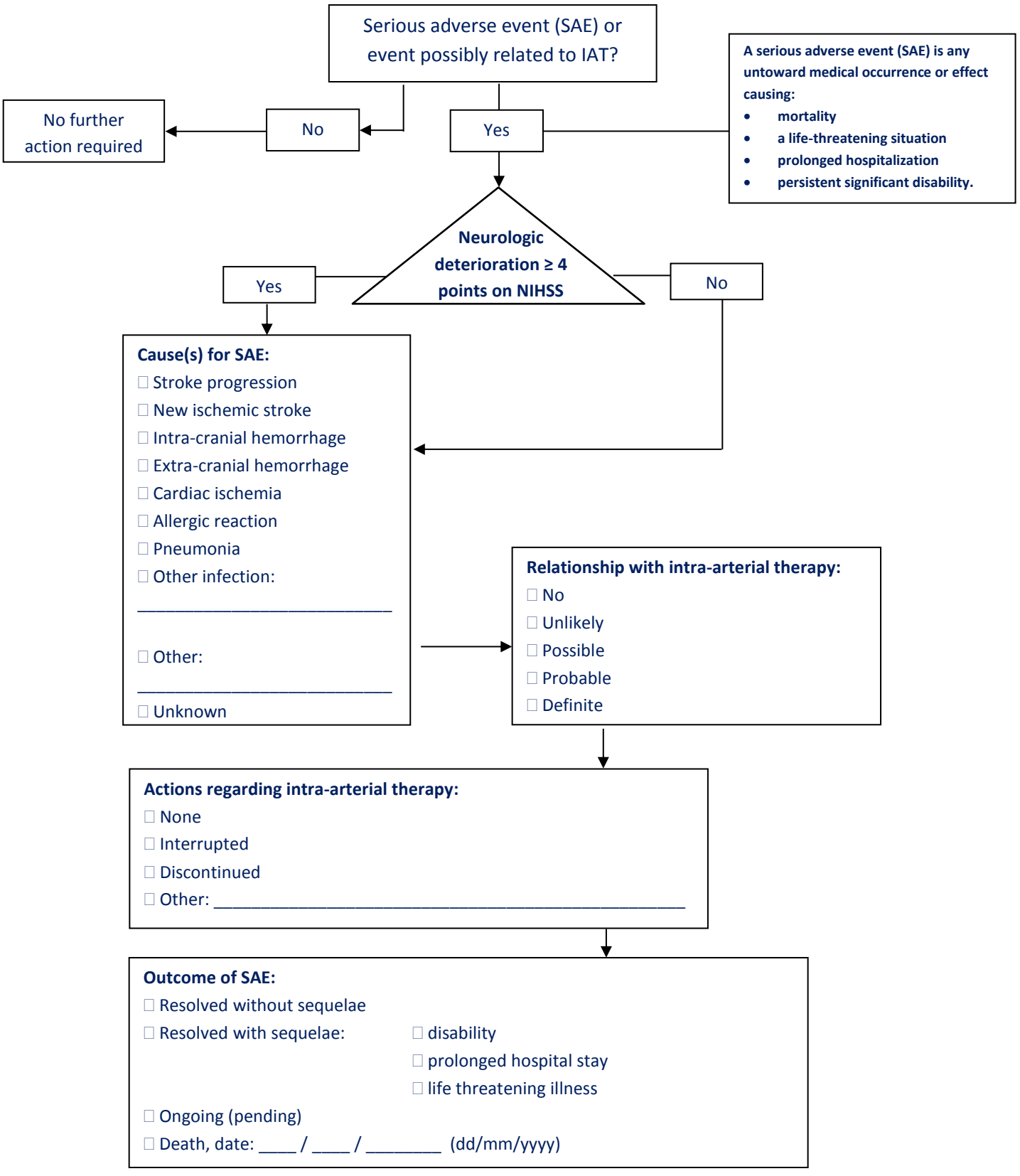
Phase of occurence:
- ☐ Baseline
- ☐ Peri-interventional
- ☐ Within 24 hours
- ☐ Between 24 hours and 48 hours
- ☐ Between 48 hours and discharge
- ☐ Between discharge and 3 month follow up

Physician name: _____

Physician signature: _____

Date of SAE registration: _____ / _____ / _____
(dd / mm / yyyy)

Please fill out the SAE flow chart:



SERIOUS ADVERSE EVENTS (SAE) FORM 3

Study number: _____

Date of SAE onset: _____

Date of SAE resolution: _____

Physician name: _____

Physician signature: _____

Date of SAE registration: _____ / _____ / _____
(dd / mm / yyyy)

Phase of occurence:
- ☐ Baseline
- ☐ Peri-interventional
- ☐ Within 24 hours
- ☐ Between 24 hours and 48 hours
- ☐ Between 48 hours and discharge
- ☐ Between discharge and 3 month follow up

Please fill out the SAE flow chart: