

ARCTIC-I Appendix 10 – Glossary to Data Collection Form

The Data Collection Form corresponds to the online CRF (eCRF) item by item. For the eCRF (the user interface of the database), you can get separate instructions from ARCTIC-I@esaic.org.

- 1 The Subject ID (ccc-hhh-ppp) is composed of a 3 digit code for the country, hospital and individual patient number, respectively. You will receive the country and hospital code from ESAIC and they (ccc-hhh) will not change throughout the study.

In contrast, the individual patient number (last triplet, ppp) will be assigned by you by just counting up from 001 to 999.

- 2 Signed ICF is required unless your IRB has waived this requirement.

If a representative has given consent, enter date of representative's signature on App. 6C.

If the patient has given consent, enter date of patient's signature on App. 6B.

There is a detailed outline in the protocol about how to approach to IC (protocol section 8.2).

- 13 Onset of stroke known: The onset of new stroke symptoms was witnessed by another person and the time of onset was communicated to the hospital.

Onset of stroke unknown: When the patient is found with the new stroke symptoms – like in case of a wake up stroke.

It may also be that no one can tell when the symptoms started or the patient was last seen without the symptoms, and the indication for thrombectomy is based on imaging criteria alone. In such cases, tick 'unknown' and leave date and time blank.

- 16 NIHSS = National Institutes of Health Stroke Scale. This symptom severity scale is routinely used by the admitting neurologist. It can be copied from the patient file.

- 17 ASPECTS = Alberta Stroke Program Early CT Score. This score is used by the (neuro-)radiologist to assess early ischaemic changes on cranial CT. It can be copied from the radiology report.

- 18 Tick all the vessels that are acutely occluded. Multiple choice is possible, e. g., distal ICA + proximal MCA + ACA for carotid T occlusion, or proximal ICA + distal ICA for a tandem lesion.

- 25 If the anaesthesia team was notified too late and could not arrive in time, tick 'not available'.

- 32 Tick yes if sedation or stand-by was chosen as a primary approach but during ongoing thrombectomy, general anaesthesia became necessary and was induced.

If yes: Enter date and time when the first drug for induction of general anaesthesia (opioid, sedative or hypnotic) was injected.

- 36-41 Medication used in the angio suite. If sedation was the primary approach but general anaesthesia was induced later, tick medication used to institute and maintain sedation.

- 37 Sedatives and/or hypnotics used to establish the desired level of sedation (or anaesthesia).

- 38 Sedatives and/or hypnotics used to maintain the desired level of sedation (or anaesthesia).

- 42 General remark concerning the table 'physiologic values':

In the first five rows, you can enter values every two minutes. If a given value is missing, cross out the respective field.

The intervals become larger as the procedure progresses. If, for example, there are no values in minute 20 because blood pressure was only measured every five minutes in a

hemodynamically stable patient (e.g., in minutes 18 and 23), take the values that are closest to this time (in the given example, from minute 28).

Time elapsed (first column):

The increasing ‘delta’ times in this column (+2 min, +4 min, ...) are relative to the ‘time of beginning’. As defined above, the beginning of anaesthesia, sedation or standby be time of first injection (of a sedative, hypnotic or opioid) – or the time of decision not to sedate the patient at all.

Systolic, mean and diastolic BP (second, third and fourth column):

Copy the blood pressure values from the anaesthesia record regardless whether they were determined invasively or non-invasively. If you have both at a given time, choose the one that you find more trustworthy. If no mean BP is available, calculate mean BP using the formula: MBP = DBP + (PP / 3) with

- MBP = mean blood pressure
- DBP = diastolic blood pressure
- SBP = systolic blood pressure
- PP = pulse pressure = SBP - DBP

- 43 Temperature irrespective of measurement site.
- 44 RASS (Richmond Agitation Sedation Scale) – during the study period, we suggest that you routinely note the RASS in the anesthesia record when you take over the patient.

Please base your assessment on the following descriptions which you might print out and place at the anaesthesia workplace.

Please assess RASS when you take over the patient and note in the anesthesia record.		
RASS	Term	Description
+4	Combative	Overtly combative or violent; immediate danger to staff
+3	Very agitated	Pulls on or removes tube(s) or catheter(s) or has aggressive behavior toward staff
+2	Agitated	Frequent nonpurposeful movement or patient–ventilator dyssynchrony
+1	Restless	Anxious or apprehensive but movements not aggressive or vigorous
0	Alert and calm	Spontaneously pays attention to caregiver
-1	Drowsy	Not fully alert, but has sustained (> 10 seconds) awakening, with eye contact, to voice
-2	Light sedation	Briefly (less than 10 seconds) awakens with eye contact to voice
-3	Moderate sedation	Any movement (but no eye contact) to voice
-4	Deep sedation	No response to voice, but any movement to physical stimulation
-5	Unarousable	No response to voice or physical stimulation

- 45 mTICI (modified Thrombolysis In Cerebral Infarction) scores the blood flow in the cerebral vessel. This score (0 = vessel occluded to 3 = blood flow restored) is assigned by the (neuro-)

radiologist/interventionalist and should be included in the intervention report as it is the technical endpoint of the procedure.

47 Comments on the mentioned complications:

Access-site problems will either be noticed in the angio suite or later, e. g., when a retroperitoneal bleed is discovered. You should find this info in the intervention report or in the patient record.

Vasospasms, dissections as well as thrombus migration ('embolization to new territories') should be documented in the intervention report.

Intracerebral or subarachnoid haemorrhage will be visible on follow-up CT scan (usually 12 to 24 hours after ET) and will be documented in the radiology report.

Occurrence of airway injury, regurgitation/vomiting with or without bronchoaspiration, allergy or angioneurotic edema, severe bronchospasm, acute circulatory failure with CPR should be documented in the anaesthesia record and can be copied from there.

Follow-Up 90 Days After Stroke

Most important: mRS after 90 days (time window, 80 to 105 days) is the primary endpoint!

If mRS was determined as part of a follow-up examination, you can use this value. However, since patients with mRS = 6, 5 or 4 will never or rarely attend their clinical follow-up visit in the neurology outpatient clinic, we suggest that you prepare to call all of the patients included in this study.

In a number of cases, it will take a couple of telephone calls until you reach the patient, representative or the general practitioner and get the information. But please bother to do so, as mRS 90 days after stroke is the most important variable.

50 When you reached the patient, representative or the primary care physician by telephone. If you take mRS from such a clinical follow-up, write the date when the patient was examined.

53 To assess the mRS, please use the scheme on the data collection form.

54 Is there any evidence for COVID-19 between stroke and follow-up? Ask for this information on the phone. Do not bother to research in dismissal letters.