Reported event processing checklist
V7.0 4th December 2018

<table>
<thead>
<tr>
<th>Centre ID:</th>
<th>Participant ID:</th>
<th>Date of reported event / death:</th>
<th>___ / ___ / ____</th>
</tr>
</thead>
</table>

1. **TMG (Trial Management Group) review the existing reported events for this participant to identify a potential new outcome event (selected below).**¹

- **Intracranial events**
  - Recurrent intracerebral haemorrhage (this is the PRIMARY OUTCOME), Other intracranial haemorrhage, Other type of stroke, Transient ischaemic attack, Retinal arterial occlusion
    - Recurrent intracerebral haemorrhage
    - Other intracranial haemorrhage
    - Other type of stroke
    - Transient ischaemic attack
    - Retinal arterial occlusion

- **Extracranial events**
  - Acute coronary syndrome, Peripheral arterial disease, Mesenteric ischaemia, Extracranial haemorrhage, Symptomatic deep vein thrombosis, Symptomatic pulmonary embolism, Coronary artery stent or bypass graft, Carotid endarterectomy, Peripheral arterial stent or bypass graft
    - Acute coronary syndrome
    - Peripheral arterial disease
    - Mesenteric ischaemia
    - Extracranial haemorrhage
    - Symptomatic deep vein thrombosis
    - Symptomatic pulmonary embolism
    - Coronary artery stent or bypass graft
    - Carotid endarterectomy
    - Peripheral arterial stent or bypass graft

- **Death (of any cause)**

2. **TMG: obtain and redact the relevant documents**

<table>
<thead>
<tr>
<th>Document</th>
<th>Needed (Y/N)</th>
<th>Requested (initials and date)</th>
<th>Received (date)</th>
<th>Redacted (Y/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient clinic letter (if seen as an outpatient)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharge summary (if inpatient)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CD of any brain imaging performed relating to this event and Image transfer form (if intracranial)</td>
<td></td>
<td></td>
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<tr>
<td>Formal radiological report of the brain imaging performed above (if intracranial)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death certificate (if death)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PM/Autopsy Report (if death)</td>
<td></td>
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<tr>
<td>Other:</td>
<td></td>
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</tbody>
</table>

3. **TMG finalise the Reported event processing pack and give to medical assessor**

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¹ Obvious duplicates and pre-existing outcome events will be grouped and removed where applicable as appropriate. When there is any doubt about this TMG should double check with the Medical Assessor.
4. **Medical Assessor makes a FINAL DECISION** about this Reported Event:

   a) I cannot assess this because …
      …there is not sufficient documents to adjudicate
      …these reported events are not the same outcome event
      …other reason (please specify)

      Please hand back to TMG to resolve this issue

   b) This was a SAE or SUSAR

      Specify course of action, and go to question 5

   c) We already know about this event, and an Outcome Event has been created.

      Associate this new Reported Event with known Outcome Event, and go to question 5

   d) This reported event is NOT an Outcome Event and does not need adjudicated

      Please provide details, and go to question 5

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2 Please see pages 34-35 of the protocol for guidance on reporting events in RESTART. The following must be reported:

- Primary and secondary outcomes
- SUSARs (a Suspected Unexpected Serious Adverse Reaction [SUSAR] is any AR that is classed as serious and is suspected to be caused by the IMP that is not consistent with the information about the IMP in the SPC).
- SAEs which are neither outcomes (see section 9.5), nor known adverse reactions to antiplatelet drugs (see section 12.2.5 and Appendix 1), nor expected non-fatal complications of ICH (see section 12.2.6).
e) This is a new outcome event.

➢ What was the date of symptom onset for this outcome event?

____________________ / __________________ / __________________

time_to_RIA time_to_Haem time_to_Vaso

time_to_Haem_Vaso time_to_VasoP time_to_VascP

➢ Provide a clinical narrative summary of this outcome event:


➢ Allocate a final outcome event type from the list and definitions below:3

<table>
<thead>
<tr>
<th>Intracranial event</th>
<th>Extracranial event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic recurrent intracerebral haemorrhage</td>
<td>Myocardial infarction confirmed on ECG and/or troponin (STEMI/NSTEMI)</td>
</tr>
<tr>
<td>Symptomatic spontaneous or traumatic intracranial haemorrhage (not accompanying intracerebral haemorrhage)</td>
<td></td>
</tr>
<tr>
<td>Ischaemic stroke (symptom duration &gt;24 hours)</td>
<td></td>
</tr>
<tr>
<td>Transient ischaemic attack (symptom duration &lt;24 hours)</td>
<td></td>
</tr>
<tr>
<td>Symptomatic stroke of uncertain sub-type…</td>
<td></td>
</tr>
<tr>
<td>…i.e. imaging not done, imaging was of wrong type/timing to determine pathological type, or stroke-like death occurred without imaging/autopsy</td>
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<tr>
<td>Retinal arterial occlusion (monocular visual loss duration &gt;24 hours)</td>
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</table>

Symptomatic major extracranial haemorrhage
…overt bleeding plus haemoglobin drop of >3 g/dL, any transfusion with overt bleeding, bleeding requiring surgical intervention (excluding dental, nasal, skin, haemorrhoid), bleeding requiring IV vasoactive agents, cardiac tamponade, or fatal bleeding

Symptomatic deep vein thrombosis (confirmed on imaging)

Symptomatic pulmonary embolism (confirmed on imaging/autopsy)

Coronary artery stent or bypass graft

Carotid endarterectomy/stenting

Peripheral arterial stent or bypass graft

Death

Fatal outcome event…
…i.e. occurred within the 30 days preceding death

Other cardiovascular death…
e.g. due to heart failure, cardiovascular procedures, cardiovascular haemorrhage

Sudden cardiac death…
…with symptoms suggestive of myocardial ischaemia (type 3), or evidence of arrhythmia

Non-cardiovascular death

Death of undetermined cause

5. **Medical Assessor**: Please sign and date this form, and return all paperwork to the TMG.

<table>
<thead>
<tr>
<th>Signature:</th>
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</table>

6. **TMG**: Record this information in the database (create Outcome Event) and sign/date form.

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