TARDIS – Working Practice Document – No: 007

Completion of Outcome and Serious Adverse Event Form

This form is completed when the recruit either experiences an Outcome Event (any vascular event) or Serious Adverse Event(SAE) since randomisation and right up until the 90-day follow-up call has been undertaken by the Nottingham Co-ordinating Centre.

Once logged onto the Live Website, click 'continue' to be taken to the screen showing a list of participants. If the one you require is not shown on the screen then click on 'Show all Trial patients'.

The date the Day 90 is due is given in the next to last column (see below) – once done, the actual date completed is displayed.

| Log Out |

| Add New Patient | | Trial documents for downloading | Data Reports |

Total number of patients currently remaining on Trial: 22 Show all Trial patients

Trial No.	Initials	Age	Type	Randomised	Day 7	Day 35	FBC	Hospital Event	SAE/Outcome		Day 90	Scans
46	JD	63	Stroke	06 Jan 11	Follow Up	Enter Day 7	Show	At Discharge or 06 Apr 2011	2	Add	*(due 06 Apr 2011)*	Show
45	ELB	75	Stroke	23 Nov 10	Follow Up	Enter Day 7	Show	At Discharge or 21 Feb 2011	1	Add	*(due 21 Feb 2011)*	Show
44	ABC	80	Stroke	17 Nov 10	Follow Up	Enter Day 7	Show	At Discharge or 15 Feb 2011	1	Add	*(due 15 Feb 2011)*	Show
43	EEP	83	TIA	04 Nov 10	Follow Up	Enter Day 7	Show	At Discharge or 02 Feb 2011	1	Add	*(due 02 Feb 2011)*	Show

Click on 'Add' against the appropriate recruit number in the 'SAE/Outcome' column.

The options below will be displayedin the top section, and below them it will indicate whether any previous Outcomes/SAEs have already been entered for this recruit – giving some short details about these.

Choose either what kind of Outcome event this is, from the 3 options under 'Main Category of Event':

- ***Tia or Stroke***
  (includes ischaemic stroke, haemorrhagic stroke, intracerebral haemorrhage, subarachnoice haemorrhage and transient ischaemic attack) or Extension of initial ischaemic stroke

- ***Myocardial Infarction or Unstable angina or Angina***
  (including new onset angina, angina at rest or increasing angina)

- ***Bleed***
  (minor, moderate or major. Includes extradural haemorrhage, subdural haemorrhage and extraspinal haemorrhage or Anaemia.

Or, ***if none of the above*** - whether it fulfils the definition of an:

- **SAE**

Only one option can be chosen for each event. A separate Outcome/SAE must be completed for each event.

Once the correct choice has been made, click on the Add button, the appropriate screens will be displayed for completion.

All the questions in *Section A: Event Information (A1-13) on the e/CRF* and Section B: General Diagnostic Evidence…….' will need to be answered whichever event choice is made.

Section A: Event information

The following information is required:

A1 Date and Time event began
(day – month – year) from the drop-down boxes and enter the time in the 24hour format, hh:mm

A2 Whether it was 'before', 'during' or 'after' the treatment phase.

- Before – after randomisation and prior to giving any trial treatment.
- During after randomisation, up to and including day 28/30.
- After after completion of treatment period until the date of completion of the 90-day telephone follow-up.

This field needs completing whatever the randomisation result and whether or not the recruit is still taking trial medications.

A3 Date and time the event was reported to the investigator in the same format as A1 above.

A4 Give a full description of the symptoms experienced during this event.

A5 Choose from the drop-down box for sub-category of event.
The event originally chosen (TIA or Stroke, MI or Unstable Angina, Bleed, or SAE) will alter the choices shown here.

A5a. If 'other' or 'other bleed' is chosen in A5 then please describe what 'other' is or 'bleed location'.

A6 You are asked whether the event was a single episode or whether it has occurred more than once.

A7 Severity of event. The options are: mild, moderate or severe.

- If the patient has died then 'severe' must be chosen.
- See CRF for definition of bleeds and relationship to severity.

A8 You are asked if the following events occurred.
Please choose yes or no from the buttons against <u>all</u> the following options.
Yes can be answered more than once.

A8a. Death
A8b. Life Threatening adverse event
A8c. Hospitalisation or hospitalisation prolonged
A8d. Persistent or significant disability/incapacity
A8e. Congenital anomaly/birth defect
A8f. Medically important
(may jeopardise patient or need active intervention to prevent any of the above).

If A8a Death is chosen, then date of death must be entered. Life threatening must also be 'yes'.

A9 Choose whether or not this event is a SUSAR - **Suspected Unexpected Serious Adverse Reaction**

If the event is an Outcome i.e vascular event then the answer would be 'No' as it would not fulfil the 'Unexpected' criteria for a SUSAR.

If the event is not related to the study drug then it cannot be a SUSAR.

If Yes is chosen for SUSAR then the answer to question A10 below must be either 'probably', or 'definitely'

If in any doubt, please telephone the Co-ordinating Centre prior to answering this question.

A10 Relationship to study drug. Choose from the following options (one choice only):

- Definitely not
- Unlikely
- Possibly
- Probably
- Definitely

This question refers to any antiplatelets being taken by the recruit.

A11 This is a free-text box. The answer to causality must not mention anything which would unblind treatment, therefore do not name any antiplatelet drugs or mention the participant's randomisation result.

A12 Advise whether the study drug was:

- Continued
- Dose Interrupted
- Discontinued
- N/A

N/A Can only be chosen if 'AFTER' was chosen for question A2

A12a If the dose was interrupted or discontinued then enter the date of last dose taken from the drop down boxes.

A13 Click on the button next to one of the following options. Whether the patient has:

- Recovered
- Event Ongoing
- Recovered with sequelae
- Died

If 'died' chosen then A8a above must also be YES and date of death must have been entered.

A13a If Event Ongoing or Recovered with sequelae' (i.e. *the patient recovered, but with an after effect possibly due to disease, injury, treatment, or procedure.)* then please provide as much detail as possible. This field is mandatory.

Section B Diagnostic Evidence

B1 Pathological
B2 CT/MRI Head
B3 Other Radiological
B4 ECG
B5 Bacteriology
B6 Biochemistry
B7 Haematology
B8 Clinical
B9 Other

If evidence is available and any line is answered 'yes', then please add as much information as you can in the 'details' field, against the applicable field.

All the above must be answered either 'yes' or 'no'.
At least one answer must be 'yes'.

B10 Comments
This is an open text field. Please do not name any antiplatelet drugs. Give as much information as possible regarding the investigations/results etc.

Please also fax over anonymised copies of available reports related to this event i.e. ECG / CT/ MRI / Carotid Doppler / discharge letters etc. Anonymise by adding the full Trial ID on the report i.e. C999/9999/ZZZ (Centre no / Recruit trial no / Recruit initials).

After completion of Section A and B, the appropriate screen is then displayed depending on the Main Category of Event originally chosen.

TIA, STROKE or Extension of Initial Ischaemic Stroke

C1:1 Symptoms
Enter 'yes' or 'no at each drop down box for the symptoms of this event:

a. face weakness
b. arm weakness
c. leg weakness
d. side of weakness (left, right, both or N/A)
e. dysarthria
f. dysphasia
g. sensory disturbance
which side? (left, right, Both or N/A)
h. visual field loss (homonymous hemianopia)
i. posterior circulation (e.g. cerebellar,brainstem)
j. neglect
k. other

If 'yes' chosen for 'Other' symptoms then complete 'other description' at C1:1l.

C1:2 Choose from the drop down boxes regarding the length of symptoms:
0-9mins
10-59mins
1-24hrs
>24hrs

C1:3 Choose whether your participant has a diagnosis of diabetes mellitus (Yes or No).

C1:4 Enter the result of any ECGs undertaken:
SINUS
AF
OTHER

C1:5 Enter the systolic blood pressure reading.

C1:6 Choose what kind of brain imaging has been undertaken:
CT
MRI
none

If imaging has been undertaken, please complete the 'Additional Clinical Brain Imaging CRF' and enter details online.

If both CT and MRI have been undertaken for this event, then choose the last one undertaken, but complete two clinical Imaging forms – one for each scan.

C1:7 Enter the NIHSS score

C1:8 Calculate and enter the ABCD2 score

C1:9 If the event was either an 'Ischaemic stroke', 'TIA' or 'Extension of initial ischaemic stroke' then enter the likely aetiology in the following 4 options:

B1:9a probable cardioembolic ….
B1:9b probable large artery….
B1:9c proable lacunar….
B1:9d unknown……..

Yes must be selected at least once.
Yes can be selected more than once, except in combination with 'unknown'.

MYOCARDIAL INFARCTION (MI), UNSTABLE ANGINA (UA) or ANGINA

A5 – This field is where you choose whether MI, UA or Angina. Depending on which is chosen, changes the validations used in section D2.

C2:1-D2:5 Mandatory fields, at least one must be yes and date of ECG needs completing.

C2:6a-e Mandatory fields

C2:7 a-d At least one line for enzyme result needs completing and needs to be out of 'Normal Range' for MI.
Otherwise if Unstable Angina was chosen at A5, then any enzyme results must be within normal limits.

BLEED or Anaemia

A5: The sub-category specific to the area of the bleed should be chosen / or Anaemia.

Section B: Diagnostic Evidence		
B3: BLEEDING EVENT		
B3:1	Was there a fall in Hb?	Yes, >=2g/dl — A Hb fall of >= 2g/dL constitutes a Major bleed
B3:2	Number of units of blood transfused	0
B3:3	Is there a known underlying cause to the bleeding event	No
	B3:3a If yes, does the underlying event fulfil the criteria for a SAE (If **Yes**, please complete a separate SAE form for it)	[Select...]
Please also complete the FBC form for any Moderate or Major bleeds		

All mandatory fields

C3:1 What was the event? Choose either MINOR, MODERATE or MAJOR depending on the answer to C3:2 below.

≥ 2g/dl constitutes a major bleed
≥1g/dl and <2g/dl constitutes a moderate bleed
<1g/dl a minor bleed

C3:2 Enter fall in Hb from drop-down box, if applicable. *This is the fall since the baseline.* N/A should only be chosen if no FBC taken.

C3:3 enter the number of units of blood transfused. If no transfusion then enter '0'

C3:4 If there is an underlying cause to the bleeding event, choose froma the options on the drop down box. If anything other than 'no' is chosen for this field, then B3:4a also needs completing.

C3:4a If the underlying event fulfils the criteria for an SAE then a further event will need reporting.

If a MODERATE or MAJOR bleed has been chosen in the Event Information Section, then a Clinical FBC form needs completing and entering on the website.

SAE

A5 Is specific to the event being reported. Choose the appropriate sub-category from the drop-down box.

ALL EVENTS

Once all the questions have been answered to your satisfaction, enter your PIN number and click on the next button.

If you omit any of the mandatory data or any invalid data is entered, you will be re-directed back to the data entry page with the omissions/errors identified in red.

Re-enter any of the omitted/updated data and then re-enter your PIN number.

If the data passes all the validation checks, you will then be re-directed to the top of the page and requested to check through it. If you are happy with the entries, then re-enter your PIN number and **Submit** the data.

Form submission sign off - Enter your PIN:	••••
Please check your entries thoroughly before submitting **If a post mortem/autopsy has been performed, please FAX through a copy (anonymised with centre number, trial number, patient initials). Fax +44 (0)115 823 0273**	Go Back Submit

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If completing the paper CRF ensure the centre number, form submitted by, patients trial number and patients initials have been added. The paper CRF needs to be signed and dated and the data transferred onto the TARDIS website. It will then need filing in the patients trial file record.

SAEs must be reported to the Co-ordinating Centre within 24 hours.

As much information should be entered in any text box, to allow correct adjudication of the event. Also please fax over corroborating reports/letters to the Trial Office for all events.

If the patient dies before the 90 day follow-up is due and before discharge from hospital, please complete the Hospital Event Form and report the death

After submitting successfully, the example screen below is displayed:

Outcome/Serious Adverse Event Submission

Test Centre for Tardis (centre id = 002): Investigator **demoinv1** Trial No **0046** Patient's initials **JD** Type **Stroke**

Your Outcome/Serious Adverse Event for JD (Trial Number 0046) was submitted successfully.
Thank you.

If a post mortem/autopsy or ECG/CT/MRI/carotid doppler assessment has been performed,
please FAX through an anonymised copy (including centre number, trial number and patient initials).
Fax +44 (0)115 823 0273

Don't forget to upload any CT/MRI scans, if taken!

Please click here to view the data you have submitted.

Or click here to return to your list of patients.