



TARDIS - Working Practice Document – No: 006

Completion of Hospital Event form

This form is to be completed for all recruits, whether diagnosed as a Stroke or TIA and whether or not admitted to hospital.

COMPLETE AT THE SPECIFIC TIMEFRAMES GIVEN BELOW:

If Admitted to Hospital for the randomising event OR already an inpatient at randomisation:

- On day 90 (if the 90-day follow-up has been undertaken by the Co-ordinating Centre) and the recruit is still an inpatient, or
 - At discharge, or
 - On death of recruit
- whichever is sooner

If not admitted to hospital for the randomising event:

- Complete at Day 35 follow-up appointment, or
 - On death of recruit
- whichever is sooner

Log on to the TARDIS website and at the 'Add New Patient' screen as shown below, click on the 'Hospital Event' line highlighted for the patient you require

[Add New Patient](#) | [Trial documents for downloading](#) | [Data Reports](#)

Total number of patients currently remaining on Trial: 19 [Show all Trial patients](#)

Trial No.	Initials	Age	Type	Randomisation	Day 7	Day 35	FBC	Hospital Event	SAEs	Day 90	Scans
21	FF	62	TIA	01 Jun 09	Follow Up	Enter Day 7	Show	At Discharge or 30 Aug 2009	0 Add	(due 30 Aug 2009)	Show
18	JS	75	TIA	30 Apr 09	Follow Up	Enter Day 7	Show	At Discharge or 29 Jul 2009	0 Add	(due 29 Jul 2009)	Show
17	JS	75	Stroke	30 Apr 09	Follow Up	Enter Day 7	Show	At Discharge or 29 Jul 2009	0 Add	(due 29 Jul 2009)	Show
13	WV	93	Stroke	28 Apr 09	Follow Up	Enter Day 7	Show	At Discharge or 27 Jul 2009	0 Add	(due 27 Jul 2009)	Show

SECTION A

- A1 At the next screen, choose the final diagnosis of the initial randomising event, from the drop down box (ALL RECRUITS)
- A2 Choose whether patient was 'an existing inpatient' (ie had their index event in hospital), 'Not admitted' or 'Admitted' for their randomising event (ALL RECRUITS)

- A2a Do not answer this question the if patient was not admitted to hospital for the randomising event, go straight to A5 and A6 and bypass both of these fields.
- If the patient was admitted for the qualifying event, enter the date of admission in the format dd-mmm-yyy, and the time of admission in the format hh:mm
- (Remember that a patient is only classed as being admitted to hospital if they stayed overnight, if discharged the same day as their 'admission' then class them as 'not admitted')
- A3 If the patient was admitted for the qualifying event, or they were an existing inpatient at randomisation,
- Enter the date the patient is discharged/died or their 90 day follow-up date, in the format dd-mmm-yyyy.
- A4 Choose the appropriate discharge disposition at that time from the drop-down box.
- A5-A6 Record whether the patient went to an Acute Stroke Unit, or a Stroke Rehabilitation Unit at any time during their admission. If not admitted then choose 'N/A'.
- A7-A9 Record whether the patient received physiotherapy, occupational therapy or speech and language therapy.

Section B – INTERNAL CAROTID ARTERY ASSESSMENT

- B1. Enter the details of any internal carotid artery assessment, choosing from the drop down options. If an assessment has not been done, or the results are 'still awaited', indicate this, and move onto the next step.
- Once the results are received, a data correction form needs to be raised and faxed to the co-ordinating centre to enable us to input these results on your behalf (include answers for B1, B2 and B3 on the form).
- B2. Otherwise, enter the date the scan was performed and
- B3. the level (%) of stenosis indicated for both left and right sides. If a range of numbers are given – take the midway point i.e. 25-35% - enter 30%.

(See the document on the website at: <http://www.tardistrial.org/TardisFormCarotidV09.pdf>)

Section C – AETIOLOGY of randomising event whether Stroke or TIA

- C1-C4 For patients diagnosed with TIA or ischaemic stroke (or stroke type unknown), indicate the likely aetiology – please answer Yes or No to all choices as appropriate for your patient.

Otherwise choose N/A.

'Yes' can be selected more than once, but if 'No' is answered in C1-3 then C4 must be 'yes'.

Once all sections have been completed:

- Enter your PIN number, check your entries and then click on the 'next' button to submit your answers.
- If you omit any of the data you will be re-directed back to the data entry page with the omissions identified in red.
- Re-enter any of the omitted data and then re-enter your PIN number.
- Once there are no validation errors, you will be re-directed to the data entered and asked to check it. If all is correct re-enter your PIN number and re-submit the data.

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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 to the header on every page. The paper CRF needs to be signed and dated and the data transferred onto the TARDIS website within 7 days of collection. The CRF will then need filing in the patients trial file.
 - If the Hospital Event Form is completed because the patient has died, please report the death as an SAE.
 - If the patient has had any other Outcomes or SAEs, please ensure that an Outcome / Serious Adverse Event Form has been completed and entered on the website.

Please be very careful when entering the date online and scrolling down between boxes as this can change the data entered in the previous box if you have not clicked out of it beforehand.