

TARDIS - Working Practice Document No: 034

Additional Clinical Brain Imaging

All radiology scans undertaken for TARDIS participants, after randomisation, require notifying to the Co-ordinating Centre by completion of an 'Additional Clinical Brain Imaging' form.

The baseline radiology scan does not need notifying on this form, the data is already collected on the baseline form.

Data can be entered directly onto the live website and if this is done, the report requires printing after submission, checking and then requires filing in the anonymised Recruit's Trial File for audit purposes.

Enter the Live Trial website in the usual way using your personal Investigator ID, PIN and password. Never use other investigator's details or divulge yours to others.

Once successfully logged in the main trial screen for your hospital is displayed with all your trial participants.

Tardis Trial - DEMO website

Triple Antiplatelets for Reducing Dependency after Ischaemic Stroke

ISRCTN47823388

Division of Stroke, Institute of Neuroscience
University of Nottingham, Clinical Sciences Building
City Hospital Campus, Hucknall Road
Nottingham NG5 1PB United Kingdom
Tel: +44 (0)115 823 0210
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Trial Patients for Centre

Test Centre for Tardis (centre id = 002): Investigator **demoinv1**

Please select a data option for an existing patient or Add New Patient

[Log Out](#)

[Add New Patient](#) |

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

Total number of patients currently remaining on Trial: 36 [Show all Trial patients](#)

Trial No.	Initials	Age	Type	Randomised	Day 7	Day 35	FBC	Hospital Event	SAE/Outcome	Day 90	Scans
68	MGI	55	TIA	08 May 12	Follow Up	Enter Day 7	Show	At Discharge or 06 Aug 2012	2	Add	(due 06 Aug 2012) Show
67	MJA	59	Stroke	08 May 12	Follow Up	Enter Day 7	Show	At Discharge or 06 Aug 2012	0	Add	(due 06 Aug 2012) Show
65	JK	57	TIA	04 May 12	Follow Up	Enter Day 7	Show	At Discharge or 02 Aug 2012	1	Add	N/A to follow up Show
60	MAJ	59	Stroke	18 Nov 11	Follow Up	Enter Day 7	Show	At Discharge or 16 Feb 2012	2	Add	(due 16 Feb 2012) Show

Choose 'Show' under the Scans column against the patient you wish to add a new scan.

Participant's Scan List

Test Centre for Tardis (centre id = 002): Investigator **demoinv1** Trial No **0053** Patient's initials **MAJ** Type **Stroke**
 Please select an existing scan or Add New Clinical Brain Scan

[Patient List](#) | [Add New Clinical Brain Scan](#) |

[Log Out](#)

All Stroke patients must have a baseline scan.
 TIA patients do not require a baseline scan for trial entry but if they have had one done then please upload the DICOM files.
 If a scan is done for clinical reasons then please also upload the relevant DICOM files.

Cinical Scan ID	Scan Date	Scan Type	Scan Modality	Select	Upload Images
N/A	11-05-2011	Baseline	MRI	View	Show files
11	11-05-2011	Clinical	MRI	View	Show files

The next screen displayed will show the existing scans already entered for this patient – the baseline scan, if done, will be displayed on the first line (see above). If you want to the data entered at baseline then choose the 'select' column and click on 'View' against this line. You will be taken to the section of the baseline form where the entries for baseline scan is shown (fields L1-L3)

Section L: Baseline CT or MRI Head		Back to Participant's Scan List
L1	Date of scan	22 Jun 2012
L2	Type of scan	CT
L3	Please complete with regards to the baseline head scan	Ischaemia - no blood

Choosing 'Back to Participant's Scan List' returns you to the previous screen display above.

Choose 'Add New Clinical Brain Scan' and the blank Additional Clinical Brain Imaging Form is shown (partial display below).

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Additional Clinical Brain Imaging (v1.2)

Nottingham City Hospital (centre id = 001): Investigator **madrian** Trial No **0811** Patient's initials **AM** Type **Stroke**
 Please enter the scan details

[Patient List](#) | [Participant's Scan List](#) | [Log Out](#)

Section A: Scan Details		
A1	CT/MRI Scan Performed	<input type="radio"/> CT <input type="radio"/> MRI
A2	Date and time of scan (dd-mm-yyyy hh:mm)	Day: [] Month: [] Year: [] : []
A3	Why was the scan done:	
A3a	If this corresponds to an Outcome/SAE, select the SAE number:	No Outcomes/SAEs recorded
A3b	Otherwise, enter the reason why the scan was done:	<div style="border: 1px solid gray; height: 40px;"></div>
A4	The result of the scan	[Select...]

Fields:

A1 Choose either CT or MRI option

A2 Enter the date of scan from your report in the format dd mmm yyyy from the drop down options, and the time of the scan in the format format 99:99.

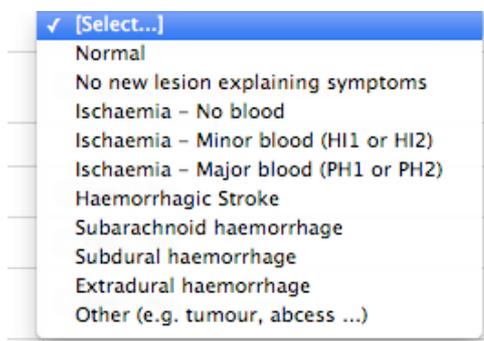
A3 Why was the scan done:

If there are any existing Outcomes/SAE records for this participant, they will be displayed in A3a, otherwise the message *'No Outcomes/SAEs recorded' will display.*

Either: choose the event, if any, relevant to this radiology report,
Or in A3b enter the reason the scan was done

You can only choose one of options A3a or A3b.

A4 Choose the result of scan from drop down box:



Fields A5 to A7– choose Yes or No for each field.

If you have actually posted your CD to the Co-ordinating Centre then please answer Yes to A7.

A8 Add any appropriate comments here in this free-text field.

A9 Radiology Report

If you are able to copy and past the text from your radiology report, then please paste into this field.

Once all fields entered correctly, enter your PIN number, the date of submission and click 'Next' (as shown below)

Form sign-off	
Please enter your PIN:	<input type="text"/>
Date form submitted (dd-mmm-yyyy)	<input type="text" value="- Day -"/> <input type="text" value="- Month -"/> <input type="text" value="- Year -"/>
Please check your entries thoroughly before submitting	<input type="button" value="Next"/>

If there are any validation errors, these will be displayed on the screen in red. Please return to the fields and update the entry.

Otherwise check through the full data again, ensure it is correct and then enter your PIN again at the bottom and press 'SUBMIT'.

Form sign-off	
Please enter your PIN:	<input type="password" value="...."/>
Date form submitted (dd-mmm-yyyy)	27 Jun 2012
Please check your entries thoroughly before submitting	<input type="button" value="Go Back"/> <input type="button" value="Submit"/>

Once submitted you will be taken to the display below where you can return to patient list, go to participant's scan list or view the data submitted – to check and/or print for the file.

Additional Clinical Brain Imaging

Test Centre for Tardis (centre id = 002): Investigator **demoinv1** Trial No **0068** Patient's i

| [Patient List](#) | | [Participant's Scan List](#) |

The Additional Clinical Brain Imaging Form for C002/T0068/MGI was submitted successfully
Thank you.

Please click [here](#) to view the data you have submitted.

Or click [here](#) to return to Patient List.

If the 'participant's scan list' option is chosen, then the newly submitted scan will be displayed with a clinical scan id number against it. This number must be quoted in any queries to the Co-ordinating Centre, or on any data corrections* related to this entry.

Participant's Scan List

Test Centre for Tardis (centre id = 002): Investigator **demoinv1** Trial No **0068** Patient's initials **MGI** Type **TIA**
Please select an existing scan or Add New Clinical Brain Scan

| [Patient List](#) | | [Add New Clinical Brain Scan](#) |

All Stroke patients must have a baseline scan.

TIA patients do not require a baseline scan for trial entry but if they have had one done then please upload the DICOM files.

If a scan is done for clinical reasons then please also upload the relevant DICOM files.

Cinical Scan ID	Scan Date	Scan Type	Scan Modality	Select	Upload Images
N/A	08-05-2012	Baseline	CT	View	Show files
14	09-05-2012	Clinical	MRI	View	Show files
7	09-05-2012	Clinical	MRI	View	Show files
5	09-05-2012	Clinical	MRI	View	Show files

Two options are now displayed: either return to the participant's list of scans, or display the data you just entered.

*Any data corrections should be made on a 'data correction form' available on the Investigator Materials website at: <http://www.tardistrial.org/jevpybki.htm>

Don't forget to fax over the anonymised printed copy of the radiology report. The report must be anonymised and the patients full trial id i.e. C999/9999/ZZ must be added.

Please also ensure that the date and time of the report is still shown.

The Demo website can be accessed at <http://www.tardistrial.org/jevpybki>.

Please login using the following details -

Investigator Id: demoinv1

Password: Nottingham

PIN: 8888