

MACE-ICH – Working Practice Document Title: Secure Vault Uploads, No. 001

Introduction:

The purpose of this Working Practice Document (WPD) is to describe the procedure to be used by site investigators for the management of uploads to the secure vault. The WPD applies to the MACE-ICH trial coordinated by the Stroke Trials Unit.

Accessing the secure vault:

The secure vault is used for sites to upload the required pseudonymised and non-anonymised documentation relating to participants in the MACE-ICH trial.

On randomising a participant, the investigator will be prompted to access the secure vault in order to enter participant contact details for the day 180 follow-up (see screenshot below).

Thank you for your submission – your randomisation record has been successfully submitted to the database.

This participant was randomised to the **Two doses of mannitol** treatment group.

1 g/kg 10% mannitol at 10 ml/min followed by a second dose 1 g/kg repeated at 24 hours, if the serum osmolality is under 320 mOsm/kg and sodium under 160 mEq/L after the first dose, in addition to standard care.

Please remember that you **must not** unblind the participant.

Please **do not** write down the treatment group.
You may wish to print this page.

- To view the data you have entered, please [click here](#).
- **Please enter the participant's contact details into the secure vault.** These will be encrypted and stored separately, **not** in the pseudonymised database that you are currently logged into for MACE-ICH.



Switch to the secure vault site

The secure vault can also be accessed at any time through the MACE-ICH database. Once the participant list is selected, a screen similar to the screenshot below will be shown.

Total number of trial participants recruited at this centre: 4
Local time: 17 Oct 2023 10:06 BST

Participant ID/age at randomisation	Event date	Randomised (day 0)	Contacts/documents	Day 1 follow-up	Day 2 follow-up	Day 5 follow-up	Day 28 follow-up	Discharge/death	SAEs	Brain scans	Protocol violations	Centre transfers	Month 6 follow-up
C002-0003	68 4 May 2023	4 May 2023	Y.NNNNN	4 May 2023	4 May 2023	7 May 2023	15 May 2023	5 May 2023	Select	Select	Select	Select	4 May 2023
C001-0004	83 20 Jun 2023	20 Jun 2023	Y.NNNNN	20 Jun 2023	20 Jun 2023	25 Jun 2023	18 Jul 2023	-	Select	Select	Select	Select	20 Jun 2023
C001-0005	43 31 May 2023	1 Jun 2023	Y.NNNNN	1 Jun 2023	1 Jun 2023	5 Jun 2023	29 Jun 2023	-	Select	Select	Select	Select	1 Jun 2023
C001-0006	57 17 Jul 2023	17 Jul 2023	Y.NNNNN	17 Jul 2023	17 Jul 2023	22 Jul 2023	14 Aug 2023	-	Select	Select	Select	Select	17 Jul 2023
C001-0007	38 17 Oct 2023	17 Oct 2023	Enter	Enter	19 Oct 2023	22 Oct 2023	14 Nov 2023	-	Select	Select	Select	Select	17 Oct 2023

In the column titled “contacts/documents”, confirmation of the uploaded documents is indicated by the Y/N and relates to: follow-up contact details, consent form(s), drug chart(s), baseline scan report, follow-up scan report, blood test results. In this column, the investigator should select the link for the relevant participant and the next page will display a link to log into the secure vault.

Uploading to the secure vault:

The secure vault should be used to upload both pseudonymised and non-anonymised documents for participant's enrolled into the MACE-ICH trial. Non-anonymised documents will be encrypted and stored separately.

As part of the ongoing monitoring throughout the duration of the trial, the following paperwork should be uploaded to the secure vault when a participant is recruited to the trial and will be reviewed by the coordinating centre:

- Consent form(s)
- Participant contact details (for follow-up)

The following documents must be uploaded pseudonymised, ensuring the participant's ID is evident:

- Drug chart(s)
- Blood test results
- Baseline scan report
- Follow-up scan report (Day 5±2)
- Participant-specific file notes as required

Scan data should be uploaded via the MACE-ICH database as opposed to the secure vault. Please see WPD 002 - Uploading Scans for instructions on this process.


Please do not send any patient identifiable documentation to us via email or fax.

Upload Process:

1. On the participant list page, hovering over the YY/NNN will show what is still required to be uploaded for that particular participant. After clicking on the link, you will be presented with the screen below.

- ⚠ Identifying information **MUST NOT** be entered into this pseudonymised database for MACE-ICH. You can use the secure vault (see below) to provide us with the participant's contact details and other identifying information, which will be encrypted and stored separately.
- i You can also use the secure vault to upload required documents for the selected participant. Please indicate the document type below, or use the 'Multiple document types' option (if you have a mix of documents in one file). If your file isn't a PDF or image, please 'print' it to a PDF first.
- i Please [click here](#) to upload brain scan images (DICOM files) for this participant.

Please choose a data type to access the secure vault

 [Select...]

Switch to the secure vault site

Existing contact details for C002-0003
(held separately in the secure vault)

Details present	Details absent	Documents
MACE-ICH centre number Participant's initials Trial number ✓ Surname ✓ Forename(s)	Middle initials Permanent address Post code Follow-up telephone number Temporary residence Alternate telephone number Email address Date of birth NHS/CHI/H+C number Hospital number Name of hospital ward(s) GP title/name GP practice name GP address GP post code GP telephone Alternate contact name Alternate contact relationship Alternate contact address Alternate contact telephone Alternate contact email Comments	None uploaded

Last updated: 4 May 2023 17:00, synchronised just now


2. This page will show you in more detail what has been uploaded for that participant as well as which contact details have been completed:
 - Required/expected documents will remain red until uploaded.
 - Documents that have been uploaded by the site but are awaiting checks from the trial office will be blue.
 - Documents that have been uploaded by the site and checked by the trial office will be marked as green and ticked.
3. To upload a document, please select the document type (or use the 'multiple document types' option if you have a mix of documents in one file) from the drop down box and click on the link to 'Switch to the secure vault site'.
4. The screen below will then be shown. Click 'choose file', select the file from your computer files and click 'upload file'.

SECURE VAULT


DEVELOPMENT DATABASE

Stroke trials office
 ☎ +44 (0)115 823 1770

[Return to MACE-ICH site](#)



MACE-ICH
 MACE-ICH – MAnnitol for Cerebral oEdema after
 IntraCerebral Haemorrhage


The files you upload using the form below will be encrypted and stored in the secure vault, held separately from the pseudonymised database used for MACE-ICH CRFs.

Please only upload a file relating to this MACE-ICH participant and the document type indicated below.

MACE-ICH participant ID: **C002-0003**


Document type: **Multiple document types**

*Please do **not** anonymise all pages prior to uploading, except for consent form(s) and do remember to write the participant ID on all documents.*

No file chosen

Accepted file formats are PDF, JPEG, PNG and GIF.

[Return to MACE-ICH site](#)


If you wish to upload a Microsoft Word document, please 'print' it to a PDF and then upload the PDF file.

5. From this page, you can also scroll down further to see the documents that you have already uploaded for that particular participant and whether they have been reviewed by the trial office yet.
6. Files must be uploaded in one of the following formats: PDF, JPEG, PNG, or GIF. If the document you are attempting to upload is currently in another format such as Word, you should go to your original document and select the 'print to PDF' option and save, this will convert the document to a PDF which you will then be able to upload.
7. On selecting the contact details, the screen below will be shown. You will be able to enter the participant's contact details straight into the database.

SECURE VAULT

DEVELOPMENT DATABASE

Stroke trials office
 ☎ +44 (0)115 823 1770

[Return to MACE-ICH trial site](#)

MACE-ICH

MACE-ICH – Mannitol for Cerebral oEdema after IntraCerebral Haemorrhage

The information you enter into the form below will be encrypted and stored in the secure vault, held separately from the pseudonymised database used for MACE-ICH CRFs. You can provide updates to this record at any time, but only the trial office will be able to see stored entries.

This is a sample form – you cannot enter data here!

Update MACE-ICH participant contact details

This page will expire in
14 minutes and 22 seconds

Please complete as much of this form as possible.

- Please make sure to include the participant's telephone number, which is required for follow-ups.

Form submitted by: **DEMO investigator**
 (Nottingham TEST hospital, NOTTINGHAM)

MACE-ICH participant ID: **C001-0004** (female, 84 years old)

Surname: (This was previously submitted) Change

Forename(s): (This was previously submitted) Change

Middle initials:

Permanent address:

8. Once all required/expected documents have been uploaded and reviewed, the trial office will be able to lock the secure vault.

Required Documentation:

Written Consent Form(s):

Upload within 1 working day of obtaining consent

The consent form should meet the following requirements:

- Printed on local headed paper
- Correct version number and date of information sheet added
- Participant name and signature clearly visible
- Legal representative name and signature clearly visible (if applicable)
- Name and signature of authorised individual receiving consent clearly visible (code J on delegation log)
- If oral consent was initially obtained, the person who took this should sign the third line of the consent form
- If consent obtained via telemedicine, the participant (or legal representative) should sign the form as well as the witness, and should be signed by the individual taking consent on their return to the hospital
- Boxes have been **initialled** and not ticked
- Signatures are dated
- The consent form should be labelled with the participant ID

Drug Chart(s):

Upload at the end of the treatment period

- For patients randomised to mannitol, sites should upload the drug chart which should document that the participant received 1 or 2 doses (as applicable).
- The timing of the initial dose should be within 72 hours of stroke onset.
- The drug chart must be anonymised and labelled with the participant ID.

Blood test results:

Upload within five working days

- Day 1 (all participants): sodium, electrolytes, eGFR
- Day 2: (participants who receive 2 doses of mannitol): sodium, electrolytes, eGFR
- All results must be anonymised and labelled with the participant ID.

Scan Reports:

Upload within five working days of assessment

- Scan reports for the baseline CT scan and follow-up CT scan on day 5±2 should be uploaded to the secure vault.
- The baseline scan should have been attended prior to randomisation (as some of the eligibility criteria is based on the results from neuroimaging at baseline).
- The scan reports must be anonymised and labelled with the participant ID.
- The corresponding imaging should be uploaded to the MACE-ICH database. For instructions regarding uploading scan data – please see WPD 002 Uploading Scans

Contact details for 180-day follow-up:

Upload within five working days of randomisation

The following information should be provided by sites:

1. Forename and Surname
2. Date of Birth
3. Permanent address
4. Follow-up telephone number
5. An alternative telephone number/address/email-address of a relative or carer
6. NHS/Hospital number
7. GP practice address and telephone number
8. Name of hospital ward(s)

File notes:

Upload within five working days

- Participant-specific file notes should be uploaded to the secure vault.
- Please use the MACE-ICH file note template which can be downloaded from the trial's documents page: <https://stroke.nottingham.ac.uk/mace-ich/docs/>
- File notes must be anonymised, with the participant ID documented.
- Please provide a detailed description of what happened, what actions were taken and the impact on participant safety.
- Please ensure that the file note is signed and dated prior to upload.