

Standard Operating Procedure: Imaging Upload for centers without XNAT connection in the CASES trial

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1. Definitions and abbreviations

CASES	Carotid Artery Stenting during Endovascular treatment for acute ischemic Stroke
CONTRAST	the Collaboration for New Treatments of Acute Stroke
CT	Computer Tomography
CTA	Computer Tomography Angiography
DSA	Digital Subtraction Angiography
EVT	Endovascular Thrombectomy
ICA	Internal Carotid Artery
MRI	Magnetic Resonance Imaging
MRA	Magnetic Resonance Angiography
PI	Principal Investigator
SOP	Standard Operating Procedure
UMCG	University Medical Center Groningen
XNAT	Open-source imaging informatics software platform

2. Aim

This standard operating procedure (SOP) describes the imaging upload process in the CASES trial. This procedure consists of providing the participating centers with information about the imaging upload. DICOM data will be uploaded from external sites to the UMCG server, where it will be temporarily stored. The sponsor will further transfer the imaging data to the lobby/pre-archive of XNAT. From then on, CONTRAST WP10 is responsible for checking the data and transferring it to the HealthRI XNAT server.

3. Range & responsibilities

This SOP is intended for the local Principal Investigators (PI's) and for all qualified research assistants (including research nurses) involved in the downloading, pseudonymizing and uploading of imaging data in the CASES trial.

Users at external sites are responsible for pseudonymizing and uploading DICOM data to the sponsor. The sponsor of the CASES trial is responsible for maintaining access and permissions for external users. Clinical users are responsible for ensuring only data with appropriate ethics approval is shared.

4. Imaging data to be collected by the participating stroke center

For each included patient:

- A) *Baseline*: non-contrast CT brain, CT angiography extracranial and intracranial blood vessels (or MRI/MRA if this modality was used at baseline), and CT perfusion if available
- B) *24 hours*: non-contrast CT brain, CT angiography extracranial and intracranial blood vessels
- C) *EVT*: DSA imaging (images obtained in 2 directions at 2 levels (intracranial ICA and ICA at the level of the carotid artery bifurcation)
- D) *90 days*: carotid artery ultrasound report with flow velocities. When performed in a primary stroke center as part of routine clinical follow-up, the report should also be obtained by the participating EVT center and uploaded. Ultrasound imaging data (DICOM files) should not be uploaded. The carotid artery ultrasound report can be emailed to cases-trial@umcg.nl
- E) Any additional brain imaging performed
- F) Brain imaging conducted at the referring hospital must be obtained by the participating EVT center.

5. Procedure

A. Pseudonymization

All imaging should be pseudonymized and labeled with the participant’s Study ID (e.g. 30001) before sending it to the sponsor. DICOM metadata can be adjusted according to the example below, if possible. Most important is that “Patient’s Name”, and “Patient ID” are replaced by the Study ID, and that the date and time of the imaging remain unchanged.

General DICOM metadata conditions:

Tag	Description	Value
(0010,0010)	Patient’s Name	{Study ID}
(0010,0020)	Patient ID	{Study ID}
(0008,0050)	Accession Number	{Timepoint}_{Modalities}
(0010,4000)	Patient Comments	Project: mrclean_cases; Subject: CASES_{Study ID}; Session CASES {Study ID}_ {Timepoint}_ {Modalities}

Example

Tag	Description	Value
(0010,0010)	Patient’s Name	30001
(0010,0020)	Patient ID	30001
(0008,0050)	Accession Number	BL1_NCCT_CTA_CTP
(0010,4000)	Patient Comments	Project: mrclean_cases; Subject: CASES_30001; Session: CASES_30001_ BL1_NCCT_CTA

B. Upload

The sponsor will contact the participating sites. There are two ways in which imaging data can be transmitted, as explained below.

SurfFileSender

- 1) The CASES research team will send you a study participant-specific invitation (‘voucher’) for which imaging data can be sent. This will occur four times per year.

Voucher details

Issuer	t.van.elk@rug.nl
Voucher link	https://filesender.surf.nl/?s=upload&vid=dda874d7-7fb1-4ebc-a836-240f99add3bd
Valid until	22 Feb 2024

Personal message from t.van.elk@rug.nl:

Dear investigator,

Please upload the DICOM images for participant 30001.

- 1) NCCT/CTA baseline
- 2) DSA DICOM images
- 3) 24 hrs NCCT/CTA

Make sure that the files are zipped into folders to make the transfer faster.

- 2) Pseudonymize the required scans and create ZIP folders for each imaging exam. Name the ZIP folder according to study ID and imaging exam (e.g. 30001_CTA_baseline)
- 3) Upload the requested zip files and click the 'Send' button.

SURF FILESENDER

Preferred language **English**

Help About Privacy

drag & drop your files here

Clear all Select files Select directory

From : cases-trial@umcg.nl
To : t.van.elk@rug.nl
Subject (optional) :
Message (optional) :
 File Encryption

Expiry date: 22/02/2024
Recipients' language: Nederlands
[Advanced settings](#)

Send

Alternative: UMCG Sharepoint

- 1) Email cases-trial@umcg.nl with the subject "Access Sharepoint".
In the email, please provide your first name, last name, email address, mobile phone number
- 2) You will receive a link to create a guest account for UMCG Sharepoint (2-factor authentication required).
- 3) After creating this account, you will gain access to the Sharepoint CASES folder for uploading imaging data.
- 4) Sign in to the Sharepoint and upload the necessary pseudonymized files in a folder named after the patient's study ID e.g. 30001.

Documents > Imaging Upload



- 5) Email cases-trial@umcg.nl to inform the CASES research team that the files have been uploaded, using the subject line: "[center name] imaging uploaded".

C. Transfer to pre-archive of XNAT

The sponsor collects all imaging from SurfFileSender/Sharepoint. The sponsor is responsible for secure transfer of the imaging data to XNAT's lobby/pre-archive. From then on, CONTRAST WP10 checks the data. The CONTRAST imaging core lab evaluates the imaging data in batches (consisting of 50 included patients). Assessments and data are entered into Castor (eCRF).