MRI Manual

Swiss Atrial Fibrillation Cohort-Study (Swiss AF Study)

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Study Contacts

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Abbreviations

A	Anterior
AF	Atrial Fibrillation
A>P	Anterior > Posterior
CD	Compact Disc
CSF	Cerebral Spinal Fluid
DICOM	Digital Imaging and Communication in Medicine
YOB	Year of Birth
3D	Three dimensional
DWI	Diffusion weighted imaging
EPI	Echo planar imaging
FLAIR	Fluid Attenuated Inversion Recovery
FOV	Field of view
ID	Identity
L	Left
L>R	Left > Right
MIP	Maximum Intensity projection
MPR	Magnetization prepared rapid gradient echo
NEX	Number of excitations
P	Posterior
PDF	Portable Document Format
R	Right
RECFOV	Rectangular field of view
SWI	Susceptibility weighted imaging
TE	Time of echo
TR	Time of repetition
TOF	Time of flight

Swiss AF - Study Details

Protocol Title	A prospective Swiss wide observational cohort study to increase knowledge on structural brain damage and its changes over time in patients with AF
Duration	> 4 years
# of planned subjects	1200/year
MRI Visit Schedule	Baseline Year 2
Site number	01 Basel 02 St. Gallen 03 Bellinzona 04 Lugano, EOC 07 Lausanne 08 Luzern 09 Genf 10 Baden 11 Bern 12 Lugano, Cardiocentro 13 Fribourg 14 St. Anna, Luzern 15 Triemli, Zürich 16 Solothurn 17 – Genf II
Subject ID	Please note that the subject ID (subject number) you will need for logistic purposes consists of a 6-digit number 2 numbers for site ID and 4 for patient ID(consecutively given to the patient within your centre): □□-□□□□ Site ID - Patient ID
Additional source of identification	Year of Birth (yyyy)
Web portal	The internet / web portal access for the study is: **www.miac.ch/study/safs** **safs@miac.ch**

1. General Information on Logistics during the Study

The Swiss AF Study is carried out via the web portal, an internet-based platform set-up and maintained by the Medical Image Analysis Centre, Basel – hereinafter called **MIAC**.

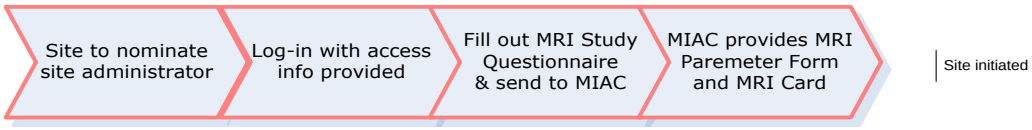
All logistic processes under the study including

- Site initiation and qualification
- Sending MR scans
- Sending and receiving study specific forms

will be handled via the web portal.

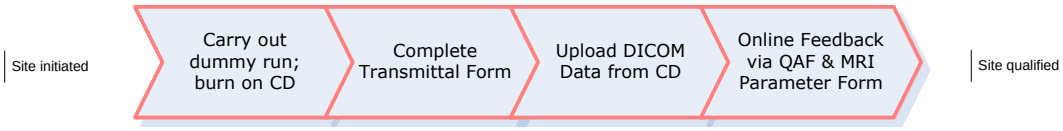
Accordingly, participating sites will fulfill the following tasks with the web portal:

1.1 Site initiation



- Nominate site administrator, preferably MRI technologist/technician of your site
- Log-in via **www.miac.ch/study/safs** in the site's favorite browser; you have to change your password upon first log-in.
- The site administrator is responsible for the information exchange "Site – MIAC". S/he has to fill out the MRI Study Questionnaire and send it to MIAC
- The site administrator can create user accounts for other site users.
- Once the site has received the OK from MIAC, it can be considered as initiated.
- The accepted dummy scan will be the reference scan for the study. Those scan parameters will be confirmed on the MRI Scan Parameter Form.

1.2 Site qualification



- For more detailed information on the Dummy run procedure, please refer to chapter 3.

1.3 Handling scans under the study

- For detailed instructions, please refer to Chapter 2.
- A sample MRI card is attached in Chapter 4.3.

1.4 "Help" Section in the web portal

- The "HELP" Section of the web portal, which can be found on the main page on the top, will support you whenever you work with the web portal.

- The 

Section contains detailed information on:

- **Site Initializiation** MRI Study Questionnaire Dummy run MRI Parameter Form MRI Card
- **Sending & Receiving** Transmittal Form Quality Assessment Form Patient List Trouble List
- **DICOM upload** System Requirements Dicom Transfer Wizard
- **Help concerning** User account User Administration
- **Downloads** MRI Technology Manual Manual for Site Administrator

1.5 Exporting DICOM data on CD / Anonymization

- When exporting the original data from the scanner disk onto CD, please make sure that the data is **anonymized** (i.e. patient ID and the year of birth but not patient initials and the full name).
- Archive the data medium (CD) at your site for future access and possible audits and monitoring. Use a media type of your choice, and if needed, follow the archiving practice of your scanner supplier or hospital standard
- Copy only the required sequences onto one CD for submission to Basel. Preferably also export only one patient to the CD.

- Complete the CD label with a water-proof marker.
- Access the web portal to upload DICOM data from this CD, as described in 1.6.

Please make sure to archive the CD with the DICOM Data!

1.6 Upload of DICOM data in the web portal

- You will use a program called Dicom Transfer Wizard in the web portal in order to upload DICOM data to MIAC.
- Dicom Transfer Wizard is a Java Applet which requires Java Runtime Environment (JRE) 1.5 or newer to be installed on your computer. Please refer to the help section in the web portal to find out if the required version of JRE is installed on your computer.
- Dicom Transfer Wizard starts automatically when you have completed a Transmittal Form for upload of DICOM data. The wizard guides through the following steps:

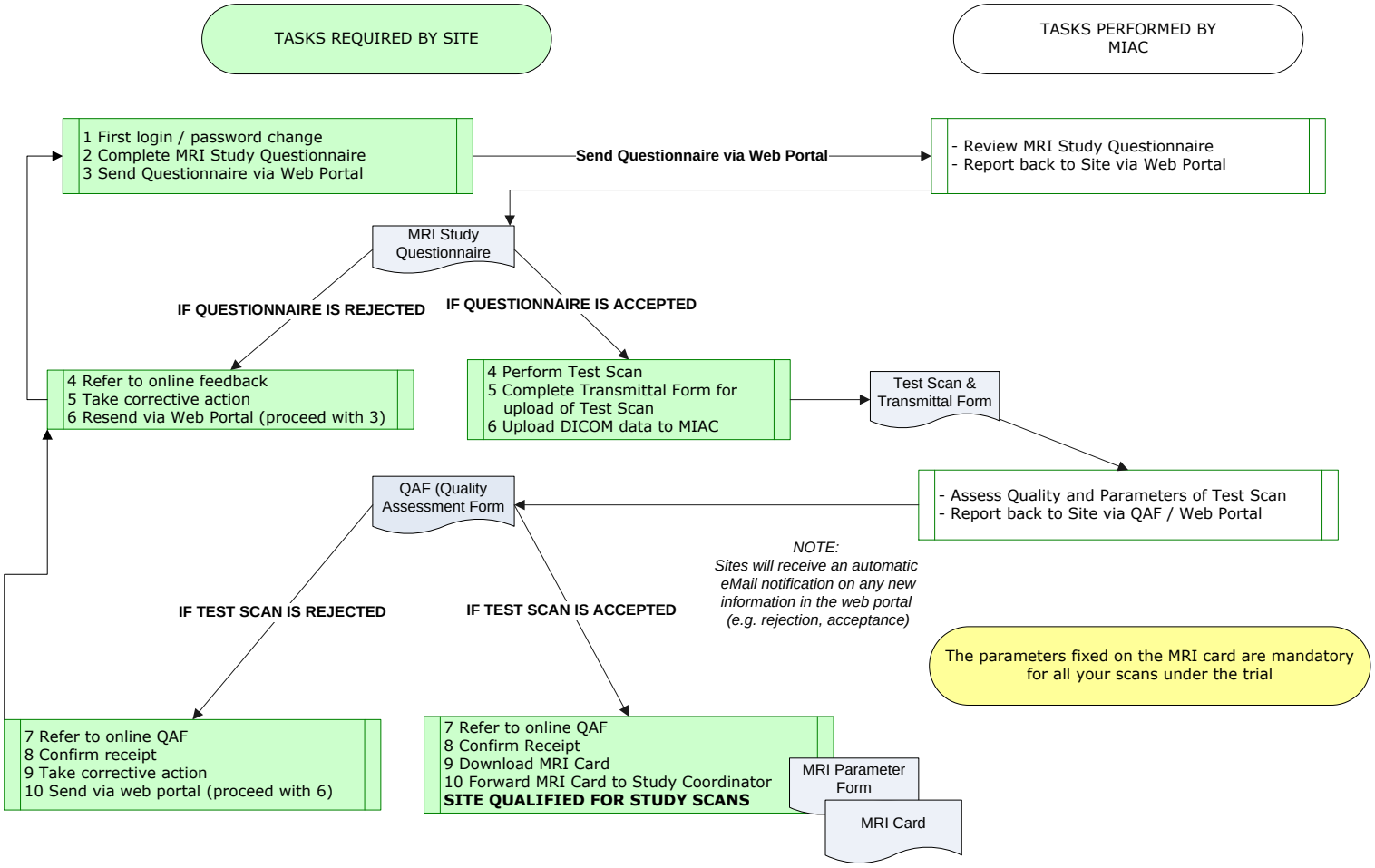
1. Select the directory on your computer from where DICOM data is uploaded. Typically just specify your CD/DVD device containing the DICOM data CD (e.g. D:\)
2. Dicom Transfer Wizard collects all DICOM images in the specified directory. Non-DICOM files are ignored and will not be uploaded
3. Review found DICOM data and confirm DICOM data is anonymized
4. DICOM data is uploaded to MIAC. Sent data is compressed and encrypted automatically

1.7 What to do if DICOM upload is not possible?

- In general, the study has been designed for complete online handling of all study specific processes.
- If, for any reason, DICOM upload is not possible, alternatively a CD can be sent to MIAC.

2. Dummy Run

2.1 Overview Site Initiation and Qualification (Dummy Run)



2.2 Description Dummy Run Procedure

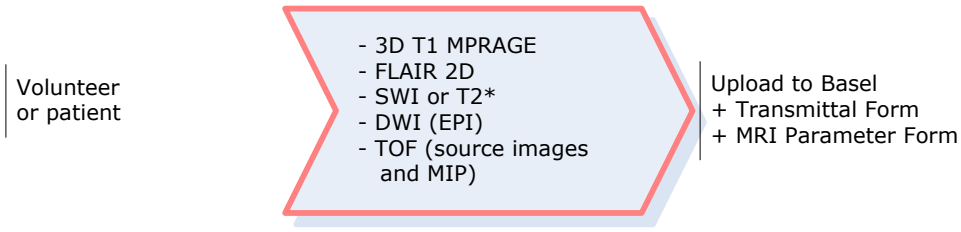
The dummy run data acceptance

- Is the **main MRI qualification** for your site to enter the study
- Is the **basis for your investigations under the study**
- Has to **reflect those parameters which produce the best scan quality on your scanner and adhere closely to the acquisition guidelines.**

Make sure to use the same scanner as used for site qualification throughout the study. A scanner change will require a new dummy run procedure.

The dummy run can be performed on a volunteer. Please note:

Your site cannot perform MRIs under the trial unless
your dummy run has been accepted by the MIAC via the QAF



2.3 Technical Instructions

2.3.1 Preparations

Head coil

For the dummy run, use the coil that is routinely used at your institution for brain imaging studies. The same head coil must be maintained throughout the study. Information on the coil must be documented on the MRI Overview Form (see sample in chapter 4) for future reference after approval of the dummy run.

If you are using a multichannel coil, please apply prescan normalize (Siemens), pure (GE), clear (Philips).

Patient comfort

Adequate padding and neck support are necessary. Please provide ear plugs, eye masks, prism glasses or other items serving patients' comfort as routinely used at your site.

2.3.2 Scouts – Localizers of the first run

Apply first a 3D scout. Then, 3 separate scout views have to be carried out as described below.

- On the T1 **axial scout** (Fig. 1), define the plane for the coronal scout perpendicular to the interhemispheric fissure
- From the **coronal scout** (Fig. 2), acquire a sagittal scout image, aligned with the falx cerebri (interhemispheric fissure)
- Carry out a **sagittal scout view** (Fig. 3, 4) as shown on table 3.3. Place the line under the border of genu and splenium of corpus callosum

Position the axial image group on the sagittal scout image, placing the center of the slice group at the inferior borders of the corpus callosum, genu and splenium (Fig. 3, 4). The slice group will then be positioned to include the whole brain from the vertex to the level of the foramen magnum. Save the localizer image with the slices shown on it to achieve the same slice positioning on subsequent scans; then make a rapid series of either T1w or T2w images (site preference) in order to check the correct slice positioning.

Make sure to save your scout images!

Fig. 1 axial

Fig. 2. Coronal

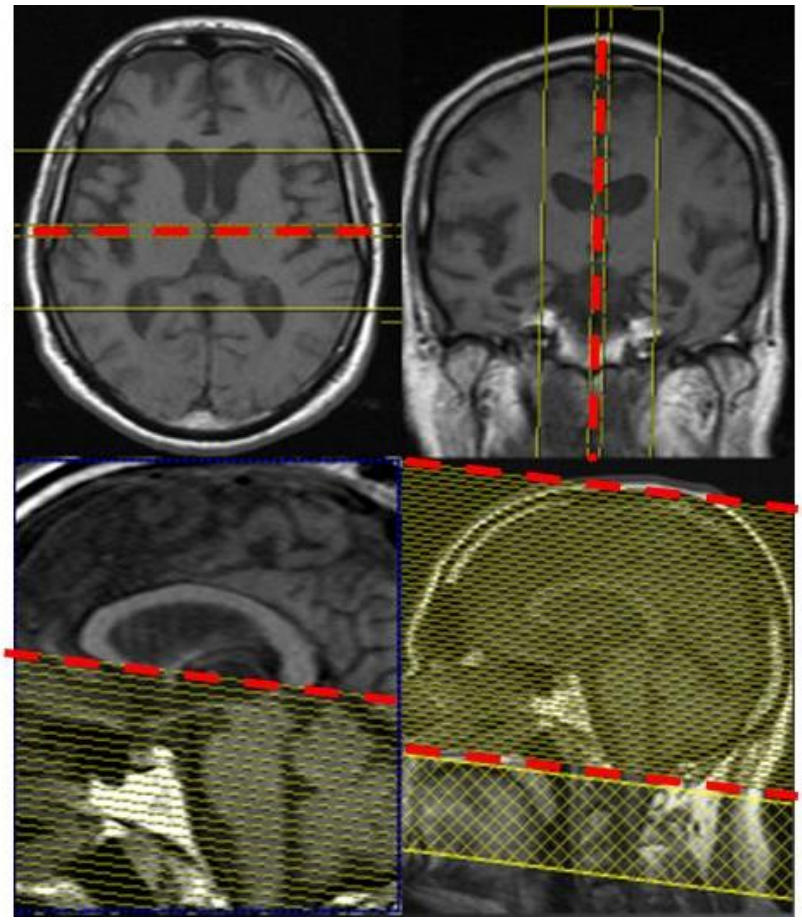


Fig. 3 sagittal magnified

Fig. 4 sagittal

2.4 Transmittal of Dummy Scan to the MIAC

Complete Transmittal Form in web portal (see sample chapter 4) and upload DICOM data using Dicom transfer wizard (please refer to chapter 1.6).

2.5 Quality Assessment of Dummy Run

Upon receipt by the MIAC, the dummy run will be reviewed within 2 working days. The following results are possible:

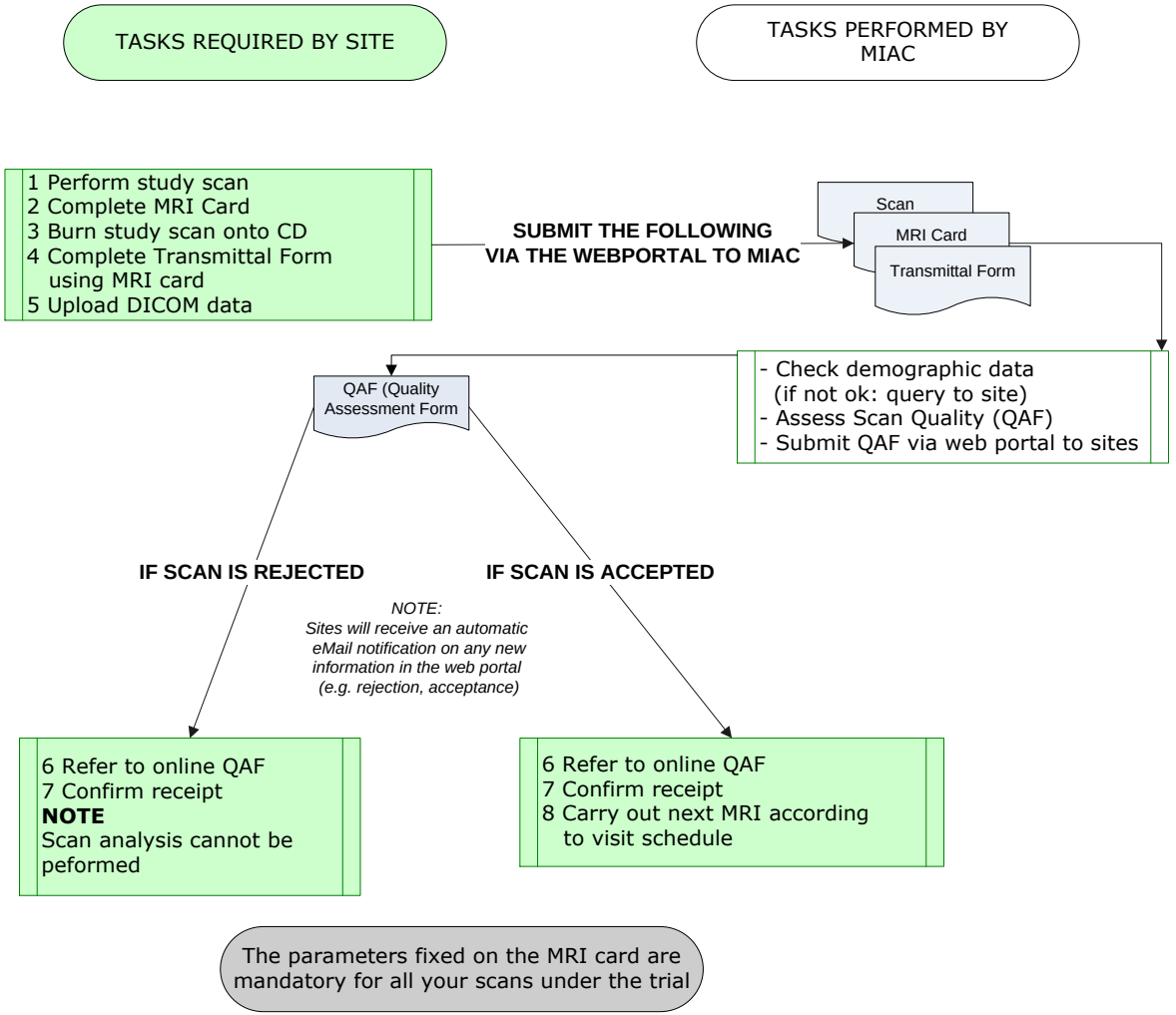
- Dummy run cannot be accepted and has to be repeated. You will find the reasons for rejection on the Quality Assessment Form on the **web portal.**
- Dummy run is accepted and you will receive an online "MRI parameter form" **(web portal)** listing the definite parameters for your site, as accepted by MIAC. Only after this acceptance, the **MRI Card** (see sample chapter 4) which you need for all patient MRIs can be downloaded from the web portal as PDF.

The parameters on the MRI card are mandatory for all your examinations under this trial!
Save the sequences on your scanner!

If your dummy run has been accepted, your site has qualified for the study and you can proceed with the study scans as shown in the visit schedule of the protocol.

3. Study Scans

3.1 Overview on study scan procedure



3.2 General Information Study Scans

3.2.1 Centre Codes and Patient ID

The responsible clinician needs to order the MRI and coordinate this with the local personnel responsible for imaging. The order form needs to include site ID, 2 digits the participating site as well as the 4 digits unique patient ID, e.g. 01-0001 for the first patient included in Basel. This code will stay the same over the entire study.

The centre codes are the following:

Basel	**01**
St. Gallen	**02**
Bellinzona	**03**
Lugano, EOC	**04**
Lausanne	**07**
Luzern	**08**
Genf	**09**
Baden	**10**
Bern	**11**
Lugano, Cardiocentro	**12**
Fribourg	**13**
St. Anna, Luzern	**14**
Triemli, Zürich	**15**
Solothurn	**16**
Genf II	**17**

Sites have to nominate a person responsible for uploading the data to the MIAC (radiology / cardiology staff). During the upload, patients will be identified again based on the patient-specific ID. This requires a close collaboration between the responsible cardiologist and radiologist at each site.

3.2.2 Patient comfort

Proper patient positioning is critical for obtaining high quality images. Correct, consistent and comfortable positioning of the patient within the head coil will limit artifacts and maximize the acquisition of good image quality.

The patient's head must be placed in a volumetric radio frequency head coil.

To minimize motion artifacts, the use of standard velcro head straps and/or foam wedges is recommended.

3.2.3 Comparability and reproducibility

For comparability purposes, please make sure

- to use the same scanner per patient, which is qualified for the study.
- to save sequences and scan parameters of the SWISS AF Study on the scanner.
- to use always sequences and scan parameters, which are confirmed on the MRI Parameter Form and on the MRI Card
- to use a reliable repositioning technique to obtain comparable MRI examinations

Please note that the MIAC has to be informed on scanner or software updates via the MRI Study Questionnaire.

3.2.4 Head coil

For examinations during the study, use the coil that is routinely used at your institution for brain imaging studies.

If you are using a multichannel coil, the Pre-scan Normalization filter must be activated in order to get good homogeneity. Always use same type of head coil for the study.

3.3 Technical Instructions

A "core" protocol for broad application was agreed upon within the Swiss AF Study centres. For reproducibility and quality assurance an initial „dummy run" will be required from each centre.

Updates of the scanner software will be accepted without additional "dummy run". Each centre is responsible for providing reproducible data. Data quality and reproducibility will be checked by MIAC and feedback will be given.

3.3.1 Core sequences/course of sequences

The following MRI protocol was agreed upon as standard for all participants in the SMSC-Study:

MRI sequence	Orientation	Slice thickness
High-resolution 3D-T1 MP-Rage	sagittal	1 mm (isotropic)
Fluid Attenuated Inversion Recovery (FLAIR)	axial	3 mm
Susceptibility weighted imaging (SWI or T2*)	axial	3 mm
Diffusion weighted imaging (DWI, EPI)	axial	3 mm
Time of flight MR-angiography (ToF, MIP)	axial	0.8 mm

Basic MRI parameters:

High-resolution 3D-T1 MP-Rage

- orientation in sagittal plane, whole brain coverage
- Isotropic voxels of 1mm required.

FLAIR, SWI or T2*

- In 2D sequences alignment should be underneath corpus callosum
- Slice thickness of 3mm without gap, 46 slices covering the whole brain
- Matrix size: 256x256, FoV 256x256 (inplane resolution 1x1mm)
- NO interpolation
- Phase encoding should be from right/left
- If multichannel coil a Pre-Scan Normalization filter is required

DWI

- inplane resolution 2x2mm
- phase encoding should be from anterior to posterior

TOF

- 3 slabs at 40 slices

4. Quality Assessment of Study Scan

Upon receipt by the MIAC, the study scan will be reviewed within 2 working days. The following results are possible:

- Scan received cannot be accepted for analysis. You will find the reasons for rejection on the Quality Assessment Form on the web portal**.**
  Sites have to confirm receipt of the QAF on the web portal, take corrective action for future scans.
- Scan is accepted;
  Sites have to confirm receipt of the QAF on the web portal. No further steps are required and sites can proceed with the next visit as scheduled.

4.1 Image Assessment Criteria for Scans

- Well defined anatomical structures
- Excellent contrast between gray and white matter in T1 MPRage
- Make sure the whole brain is covered
- No interpolated images
- Adequate SNR and homogeneity

4.2 Sample MRI Study Questionnaire

MRI Study Questionnaire

Swiss AF Study

Medical Image Analysis Center
University Hospital Basel
Schanzenstrasse 55
CH-4031 Basel
Phone: ++41 61 265 43 18
Fax: ++41 61 265 52 08
e-mail: safs@miac.ch

Address of your Centre:

Sitenumber: 01
Name of centre:
Street & no.:
City:
Zip or postal code:
Country: Switzerland

The responsible person at your site for communicating with Medical Image Analysis Center will be:

Name*: Alain Thoeni
e-mail*: athoeni@uhbs.ch
Phone:
Fax:

* Note: To change this information, go to "Edit your Account"!

The responsible radiologist at your site will be:

Name:
e-mail:
Phone:
Fax:

The responsible MRI technologist/technician at your site will be:

Name:
e-mail:
Phone:
Fax:

The following email addresses of users will be notified upon arrival of new information for your site:
athoeni@uhbs.ch

If required, you can enter a **comma separated (,)** list of further email addresses of staff who should be notified:

Please complete the following technical information of the MRI scanner you intend to use for the proposed Swiss AF Study:

Scanner Vendor:
Scanner Software Name:
Scanner Software Version:
Scanner Hardware Name:
Coil type/No. of channels:
Scanner Field Strength: 0.00 Tesla

Is the scanner planned to be changed before 2014? yes no
Is your site capable of providing MRI data in DICOM format? yes no
Is your site capable of providing MRI data on CD-ROM? yes no

We confirm that we read the MRI manual of the Swiss AF Study. Our sequence parameters correspond to the protocol and will not be changed throughout the study.

yes

4.3 Sample MRI Card

Swiss AF Study

MRI CARD

Instructions for study coordinator: Complete the information requested in the boxes below and pass on to the MRI technician at the time of the patient scan (hand over the card to the patient before sending him/her to the MRI department).

Basel 01 Principal Investigator: .....

Sitenumber	Patient ID (e.g. 0001)	Year of birth (yyyy)	Subject's weight in kg
01			

Visit: **Baseline** ☐ **Year 2** ☐

Instructions for MRI technician: check the following before patient leaves, give reason for deviation. Use this card to complete the Transmittal Form in the Medical Image Analysis Center web portal.

Date of scan (dd/mmm/yyyy): _____

MRI check list:	Yes	Comment
MRI header: Patient ID corresponds with MRI Card	☐	
Scout views and reconstructed **MIP sequence** are recorded	☐	
ToF sequence covers the **circulus willisi**	☐	
All other sequences cover the **entire brain**	☐	
Sequences are **not interpolated**	☐	
T1 MPR sag:		
• Slice thickness 1.0 mm / Inplane res. 1.0x1.0 mm^2	☐	
• TR 2000 ms / TE 4 ms / Inversion time 950 ms	☐	
Flair:		
• Slice thickness 3.0 mm / Gap 0.0 mm / Inplane res. 1.0x1.0 mm^2	☐	
• TR 9000 ms / TE 130 ms / Inversion time 400 ms	☐	
SWI/T2*:		
• Slice thickness 3.0 mm / Gap 0.0 mm / Inplane res. 1.0x1.0 mm^2	☐	
• TR 40 ms / TE 40 ms	☐	
DWI:		
• Slice thickness 3.0 mm / Gap 0.0 mm / Inplane res. 2.0x2.0 mm^2	☐	
• TR 600 ms / TE 100 ms	☐	
ToF:		
• Slice thickness 0.8 mm / Inplane res. 1.0x1.0 mm^2	☐	
• TR 13 ms / TE 7 ms	☐	
Orientation and position of the slices in the sequences are:		
• identical in Flair and SWI/T2*	☐	
• identical in actual scan and in baseline (for followup scans)	☐	

_____ _____

MRI technician signature Date

4.4 Sample Transmittal Form

Transmittal Form

for upload of Dicom data

Swiss AF Study

To:
Medical Image Analysis Center
University Hospital Basel
Schanzenstrasse 55
CH-4031 Basel

Phone: ++41 61 265 43 18
Fax: ++41 61 265 52 08
e-mail: safs@miac.ch

From:
Basel (Site 01)
University Hospital Basel
Switzerland

Patient Information

Patient No.	Year of birth	Date of scan	Visit
01-0001	1974	21/Feb/2014	Baseline

Date sent: 24/Feb/2014
Form sent by: Alain Thoeni

4.5 Sample Quality Assessment Form

Swiss AF Study

Quality Assessment Form

Sitenumber	Patient ID	Year of birth	Date of scan	Visit
01	0001	1974	21/Feb/2014	Baseline

	Acceptable	Description
Data Source		
Electr. Transfer	yes	
Data Format		
DICOM	yes	
Data Layout		
Number of sequences	yes	
Number of slices	yes	
Contrast	yes	
Scan Quality		
GAP/Slice thickness	yes	
Parameters	yes	
Repositioning	yes	

Scan has been accepted for analysis - No further MRI follow-up required