



Dear Swiss-AF Study Teams

More than two years after the official start of Swiss-AF we have made substantial progress. More than 1750 patients have been enrolled in this cohort, making it one of the largest of its kind worldwide. To make Swiss-AF even more valuable, we will need to continue our efforts and try to extend the study as long as possible. The next prolongation grant to be submitted to the SNSF will be due next year. To have a chance of success, we will have to demonstrate that recruitment will be done by next year, which is clearly possible if we maintain the good recruitment rates observed over the last weeks. If we continue to enroll at least 18-20 patients per week, the goal of 2400 patients will be reached in summer 2017. I would like to thank all the Swiss-AF study teams for their continuing efforts towards this important study.

It is also important to mention that some changes in the study lead have not affected the overall course of the study! As many of you know, I recently moved to Hamilton, Canada, where I am now working as a clinician-scientist. I will continue to stay closely involved in the day-to-day management of Swiss-AF and support Stefan Osswald in leading the study. We are also about to re-assemble the local study team around Michael Kuehne, such that he will be able to support Stefan in the grant submission next year.

Please contact the Swiss-AF study team in Basel if you have any questions.

Best regards,


David Conen



Follow-Up 2:

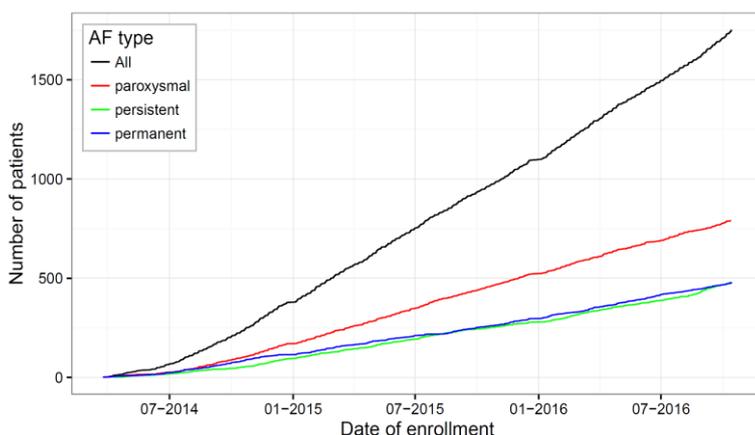
Follow-Up 2 visits must be completed after 2 years +/- 4 weeks. The following exams are needed:

- Study CRF
- Clinical measures
- Resting ECG
- Cognitive assessments
- QoL and disability
- AF-related resource use and costs
- Clinical outcomes (incl. ICD-10 codes)
- Blood sampling
- **Brain MRI**

The follow-up MRI is of key importance, as the assessment of changes in brain structure over time is one of the central aims of Swiss-AF.

If it is difficult to convince the patient for another visit at the center:

- Try to make a **home-visit** allowing to do blood sampling and neurocognitive tests. All centers are welcome to do this for **all FU visits**. Each home-visit will be compensated with 255 CHF.
- You may pick up the patient from home (car-sharing, taxi). Costs will be reimbursed.
- Remind the patient that MRI includes **no contrast medium** and that measurement time is no longer than 20-25 minutes.
- Claustrophobic patients can receive Dormicum nasal spray for their comfort.



To date, 1758 patients are included in Swiss-AF (goal: 2400).

About 52% of FU-1 visits and 11% of FU-2 visits are completed.

Swiss-AF Team Profiles

In each newsletter we introduce teams of our actively participating sites. Here, we are pleased to introduce the study team at **CHUV, Lausanne** as well as the teams at **HUG, Genève**, and **Hôpital des Trois-Chêne, Genève**.



Team of **CHUV, Lausanne** (from left to right):
PD Dr. med. Jürg Schläpfer (PI), **Sandrine Salzmann** (Infirmière de recherche), **Nathalie Lauriers** (Coordinateur recherche).

« **Swiss-AF est une étude ambitieuse qui donnera des renseignements** de première valeur sur la prise en charge de la fibrillation atriale en Suisse, sur ses conséquences et ses implications socio-économiques. Les patients que nous incluons sont déjà curieux d'en connaître les résultats! »

(Study Team CHUV, Lausanne, May 2016)



Team of **Genève** (from left to right):
Elise Guillermet (HUG study coordinator nurse), **Hervé Gallet** (3 Chênes study nurse), **Dipen Shah** (PI), **Patrick Perret** (3 Chênes study nurse); not on the photo are Dr. Georg Ehret (3 Chênes) and Dr. Cheryl Terres (HUG).

Update Health Economics

- **All patient aged 45-65** years should complete the **absenteeism questionnaire**. A **FU** version of it needs to be completed at all visits.
- **Please send your completed FU work absenteeism** questionnaires to Fabienne Witassek by regular post or E-mail (keep copies of it). As yet, 131 Baseline forms, 65 FU-1 forms (and one FU-2 form) were sent in.
- **Patient diaries** distribution is completed (German copies: N= 164 / French copies: N= 54). A **new exemplar** needs to be handed out at **each FU visit along with careful instructions how to use it**.
- The yearly HE data transfer was completed. Next date of transfer: **June 30, 2017**. All patients will be included again, so you may re-use your recent data files next year, adding the new patients to the excel tables.
- Each patient included in the recent data transfer will be reimbursed with **30 CHF** at the current round of compensation (3rd quarter, 2016).



Notes & Hints

- **Recruitment continues** until 2400 patients are recruited (target date: summer 2017).
- All centers can recruit patients aged **45 - 65** years with AF history of at least 3 years (and patients aged ≥ 65 years with paroxysmal AF documented at least twice within 5 years or with persistent AF documented within 5 years).
- Patients who fulfill the inclusion criteria but **refuse to do an MRI** (or have a **clear contraindication**) can be included: Pacemaker clinics should be screened to identify eligible patients even if they cannot undergo brain MRI imaging.
- Updated **Patient Informed Consent Forms** (de/fr/it) were provided in September (approved by EKNZ for all centers).
- **Major events** need to be evaluated by two local reviewers. The Event Reviewer Accounts have been distributed to the centers. Local documents will be collected at a later point in time.

Unplanned hospitalizations that are **not linked to major events** do not require full documentation. However, please indicate the reason for hospitalization in eCRF (optionally, a brief report may be added).

- For each major event that has been evaluated and documented in the appropriate eCRF form on SecuTrial, **150 CHF** will be reimbursed.
- The **MMAS** (medication adherence form) should be completed with all patients at all visits (approved by EKNZ for all centers). Each MMAS documented in the eCRF will be reimbursed with **50 CHF**.
- As Fabian Zraggen has left Schiller AG, please contact Ramun Schmid for technical issues regarding Swiss-AF devices:
Ramun.Schmid@schiller.ch; Ph: +41 41 766 42 80.

Deadline for the next compensation of study costs: Dec 31, 2016

Visits and MRIs provided after the cut-off date will be considered in the next round of compensation, as usual.

Keeping up eCRF quality

- **Please check your eCRF data** regularly:

Click on the following links in secuTrial: `Reports` (see Welcome page) and `To Do List`. Then click on items that are indicated for correction.

- By clicking **“Definitely saved and closed”** at the end of each form, you confirm that missing data in this form could not be added, even if efforts were being made, and must be accepted as lost. So it is very important to **check your data** before clicking this button.
- **Please delete incorrect eCRF entries.** Radio button entries can be changed by double-clicking the button.
- If a form is blank and cannot be completed (e.g., due to FU by phone), do not save it - leave it blank (so no “missing data” feedback will occur).
- If a form will never be completed due to drop-out/study termination, you can delete it:
 1. Complete Study Termination Form
 2. Click:
 - Edit Visit Plan (Menu line at the top)
 - Delete (e.g., FU Visit)
 - Preview Visit Plan and complete the “Reason for modification”
 3. SAVE to finish
- If you deleted a blank form only by mistake, you can create a new form (click on “Next visit” – “New form”).



Swiss-AF is funded by: