

ANNUAL REPORT 2008

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1 Foreword and Editorial

1.1 Foreword by the President

Dr. Hans A. Schwarz, President of the SCQM Foundation

For the SCQM, 2008 proved to be a crucial year. In accordance with the business plan for 2007 – 2011 and considering the possibilities of modern communication technology, the Board decided to prepare an online version of the three registries. This online data base is to better answer the increasing demand of much quicker feed-backs, better data-cleaning, easier extractions of data for studies and more empowerment for patients wishing to have online access to their own data, as well as the possibility to react to special requirements for special project studies. The system chosen is an open-source system, based on the Danish Danbio model, adapted and run by Seantis, Switzerland and Zitelab, Denmark. There was a tremendous amount of work to be done by both Seantis & Zitelab (F. Reinhard and N. Steen Krogh and teams respectively) and the SCQM team, led by Dr. Almut Scherer and Mrs. Sabine von Känel, most valuably assisted by Dres. Axel Finckh, Geneva, PD Burkhard Möller, Berne and the office team. Thanks to their work a pilot version was started at the Inselspital Berne towards the end of 2008 and has been improved and used by ever more participants in private practices and clinics. By mid-2009 every participant should be able to go online.

A careful transfer of the data from the existing data base to the new one was time-consuming but essential in order to have the full set of data since 1996. While funding is a perpetual worry of any Board of a non-profit organization, the SCQM takes no exception to this. We are very grateful indeed for the lasting support by our patrons and sponsors. In 2008 we have to thank especially for a generous donation by the Swiss Society of Rheumatology, a decision unanimously approved by the attendees of the Annual General Meeting in Zürich. By this token the Swiss rheumatologists underlined the important role of SCQM for physicians, patients and the Swiss Society of Rheumatology, SCQM being one of its hallmarks. Moreover, a very generous and swiftly approved loan from the Verein Balgrist, Zürich (interest-free), on the initiative of Prof. Dr. R. Kissling, helped us to master a financial bottleneck.

My sincere thanks go to every one of those mentioned above and to all our colleagues who continue to support SCQM by including and following their patients in our registries.

1.2 2008 – a year of development

Sabine von Känel, Executive Secretary of the SCQM Foundation

The year 2008 was a year packed full of decisions and development, that were needed to prepare SCQM for the future. In February 2008, the Board of the Foundation approved the business plan, that was produced by the company Froidevaux, Eicher & Partner. One of the central recommendations of the business plan was the switch to an online data base. An online data base would

prepare the SCQM best for the future needs, for example the need for a higher coverage of Swiss patients with inflammatory rheumatic disease, that would not be possible with centralized manual data entry with the currently available financial means. Moreover, an online solution would facilitate considerably the communication with the participating physicians. Finally, a solution was needed for the numerous technical problems brought about that the data base operative in 2007 and 2008.

In May 2008, the board of the SCQM evaluated the proposals for the development of the online database. Only one month later, the Board of the Foundation decided who was to develop the online database, and at the same time, financial means for the development were found. First of all by an interest free loan by the Society Clinic Balgrist and later on by a generous donation by the Swiss Society of Rheumatology. The development mandate was given to the Swiss company Seantis and the Danish company Zitelab, who had developed the Danish online registry Danbio.

The first development steps were done very quickly. The main hurdle at hand was the migration of the data-base into the online data-base. A substantial amount of data-cleaning was needed for this migration. In November 2008, Dr Burkhard Möller of the Inselspital Bern was intensely involved in testing the online database, and gave us extremely valuable feedback on the system.

A further recommendation of the business plan was to increase the external communication. This was implemented by regular mailings of a “news-letter” to the contributing physicians and by the presence of all patron members at the meetings of the board of the SCQM foundation. In quarter 4 of 2008, the SCQM webpage was redesigned. Furthermore, the SCQM was present with a stand at most Swiss rheumatology meetings, which allowed us to contact and inform many users.

End of 2007 marked a change in internal operative procedures. The administrative and scientific management was separated and lifted to a more professional level. In addition to the administrative lead (Miss S. Von Känel), we were able to fill the position of a scientific manager in April with Ms. Dr. Almut Scherer.

Since the SCQM, which originally collected data of only patients with rheumatoid arthritis, was extended with registries for ankylosing spondylitis and psoriatic arthritis, the name of the SCQM was changed into “Swiss Clinical Quality Management in rheumatic disease”. This name allows for future integration of other rheumatic diseases in the SCQM.

At the start of the year, a dicomizer, partly financed by the Rheumastiftung Zürich, was purchased, to allow us to scan and digitize x-ray films for the cohort of ankylosing spondylitis. This scanning process takes place in the SCQM office. Images are then made available for scoring by the ankylosing spondylitis scientific working group (see section 8.4). These x-ray read-out sessions take place under the lead of Dr. Ueli Weber at the University Clinic Balgrist in Zürich.

On the scientific level too, the SCQM wants to set course for the future. Research regarding the inflammatory rheumatic diseases is currently focussing on genetic studies concerning the susceptibility to a disease, its course and the responsiveness to treatment. Under the lead of Prof. Cem Gabay, vice president of the SCQM and president of the SGR, a proposal for a bio-data base (blood samples) was therefor submitted to the Swiss National Science Foundation. If and in what form this project can be realized will become clear in the near future.

A task force for the development of *rules of procedures for research and collaboration* was formed in November of 2008. The work of this task force will increase the transparency of access

to data and authorship for work based on SCQM data.

Last but not least, the SCQM is aiming to find a broader financial base. At the end of 2008, a professional fund raiser was commissioned to find new financial sources for the SCQM. In these economically harsh times, this is not an easy task.

1.3 Staff and office

The SCQM office moved from the center of Zürich to Altstetten in June of 2008, since the central location ceased to suffice in terms of desk- and storage space.

In 2008, Ms Claudia Cutler, Ms Marion Täscher Furger and Ms Rowena Laue left the SCQM to pursue new challenges. We thank them for their engagement for the SCQM.

Mirta Viviani joined us and took over Ms Täsch's task of scoring x-rays of RA patients. She was trained by Dr. Adrian Forster in methods of RatingenRau scoring method. We furthermore had temporary staff, to help us with data-entry and scanning of the RA and AS x-rays. Susanne Frieser joined us mid April as data manager for the registry for PsA with a work load of 20%. As mentioned in the yearly report 2007, Dr. Scherer started her position as scientific manager with SCQM in April 2008. In 2008, she was mainly responsible for the development of the online database.

After having been with us for 6 years, Dr. med. A.-M. Chamot resigned from the foundation board. We are very grateful for her engagement for the SCQM. We are glad to have won Dr. M.-J. Sauvain as representative of practice based rheumatologists to replace Dr. Chamot. Dr. Sauvain is also our representative of the Inselhospital, where she works in pediatric rheumatology in the Children's Clinic.

1.4 Perspective 2009

The process of bringing SCQM from paper to online is, of course, a continuing one. We hope to have all users online by the end of the year 2009. Although the switch from paper to online brings about additional work for the users, who have to familiarize themselves with the new system and set up their own working procedures of how to use the system, the value of the online database is tremendous. It gives the rheumatologists who contribute data full access to their data, and provides a flexible research tool for the scientific community in Switzerland.

The online database will undergo an intensive round of development in the coming half year, and will then continue to develop on a slower pace.

2 Contributors to the SCQM registry

All patients in the SCQM registry are included in one of our three cohorts, that is, Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA) or Rheumatoid Arthritis (RA). A written consent is required by all patients prior to study inclusion. The only prerequisite is being able to communicate in French, German or Italian. Participating SCQM rheumatologists are based in private practices, (private) regional hospitals and university hospitals.

Patients	Institution
11	Medizinisches Zentrum Bad Ragaz
12	RehaClinic Zurzach
13	Hôpital La Chaux-de-Fonds
14	Zürcher Höhenklinik Davos
17	Höpital cantonal Fribourg
18	Zuger Kantonsspital
26	Thurgauer Klinik Diessenhofen
28	Stadtspital Triemli Zürich
30	Hôpital Régional Delémont
33	Kantonsspital Schaffhausen
34	Felix Platter Spital Basel
36	Reha Schinznach
48	Bürgerspital Solothurn
50	Kantonsspital St. Gallen
54	Bethesda-Spital Basel
55	Schulthess Klinik Zürich
63	Centre hospitalier universitaire vaudois Lausanne
76	Kantonsspital Winterthur
79	Kantonsspital Luzern
87	Hôpitaux Universitaire de Genève
108	Kantonsspital Aarau
116	Universitätsspital Balgrist Zürich
151	Inselspital Bern
405	Universitätsspital Zürich
1603	Sum of patients in hospitals (all hospitals)
2588	Sum of patients in practices (206 practices)
4191	Sum of active SCQM patients (RA and AS)

Table 1: “Active” patients (only ankylosing spondylitis and rheumatoid arthritis) by hospital. Patients were considered “active”, if there had been at least one visit for them in the data-base between the 1st of January 2007 and 31st of December 2008. It should be noted that the sum of patients contributed by hospital institutions is greater than the numbers listed in the table, since hospitals with less than 10 patients are not listed explicitly.

Table 1 represents all hospitals that have at least 10 patients in the SCQM registry. In this table, only patients with ankylosing spondylitis and rheumatoid arthritis are taken into consideration. This is because the data of the psoriatic arthritis patients have not yet been digitalized fully, and therefore we were not able to include PsA patients in this analysis.

Amongst the private rheumatology offices there are some that contribute up to 100 'active' patients to the SCQM. Overall, almost two third of active patients are contributed by office based rheumatologists.

3 Activity Report of the Rheumatoid Arthritis Cohort

3.1 Population

The SCQM registry of rheumatoid arthritis exists since 1995. Overall there are 5132 patients and over 26'000 visits in the rheumatoid arthritis cohort (status End of May 2009). The median number of visits per patient is 4, with a range of up to 61 visits. 3004 patients were considered active, meaning that these patients had had at least one SCQM visit with a rheumatologist in the year 2007 and 2008. The distribution of the so called "active" patients is seen below, showing the actual assignment of the patients to clinics or practices.

3.2 Sample

The sampling period was set between 1st. January 2007 and 31st. December 2008, i.e. all "active" patients. Results on overall statistics are shown separately for the year 2007 and 2008 and for inclusion or follow-up visits. A follow-up visit could be either a yearly control or an intermediate control. If a patient was recorded with more than one follow-up visit, an average of the available disease activity scores was used. The analyses shown in this report were run End of May 2009.

3.3 Data collection

A clinical examination and the collection of blood samples for laboratory tests are included during initial, intermediate control and annual control visits. Patients are asked to complete patient questionnaires. The collected data (physician and patient) is communicated to the SCQM Office for evaluation. Based on this data individualized patient feedback reports are produced, and sent back to their respective physician.

3.4 Variables

Patient information includes gender, date of birth and month and year of RA diagnosis. Laboratory tests include rheumatoid factors (RF), erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP). Joint destruction is assessed based on hand and feet X-ray, which should not be older than 6 months. X-rays are scored centrally according to the method proposed by Rau et al. (Rau R, Wassenberg S, Herborn G, Stucki G and Gebler A, *A new method of scoring radiographic*

change in rheumatoid arthritis, J. Rheumatol. 1998). When a part of an image is not scorable, or not all required images are sent in, the last score is used in the data base (last observation carried forward). During clinical assessment, the physician completes a standardized questionnaire recording all prescribed medications with dosage. In addition, clinical assessment includes a 28 swollen and tender joint count, which, together with erythrocyte sedimentation rate (ESR), is used to calculate the Disease Activity Score (DAS28). In addition, questionnaires for side effects of drugs are used. Patient questionnaires include the RA disease activity index (RADAI), the Stanford Health Assessment Questionnaire (HAQ) and the SF-36 (SF36 stands for Short-form-36, and is a generic questionnaire to measure quality of life).

3.5 Results

The results of the analysis are shown separately for inclusion and follow-up visits for 2007 and 2008. Patients included in 2007 may also be in the group of the follow-up patients 2008.

3.5.1 Patient characteristics

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
number of patients	431	389	2002	1996
mean age (years)	53.69	53.85	57.59	57.64
Standard deviation	13.57	14.47	13.4	13.21
% Female	78	74.8	77.7	78.7
time sympt.-diagnosis (months)	3	3	–	–
Inter quartile range (months)	(0 - 12)	(0 - 12)	–	–

Table 2: Patient characteristics of inclusion and follow-up patients in 2007 and 2008.

Table 2 shows patient characteristics data. As mentioned above, the so called "active" patients of the years 2007 and 2008 were analyzed. There were 431 patients enrolled in the RA data base in 2007. For 2008 we received 389 inclusion questionnaires. 2002 patients had a follow-up visit in 2007, for the year 2008, 1996 follow-up visits are in the RA data base. Less than a quarter of all patients are male. The newly included patients are on an average 53.85 years old, and the mean age of the follow-up patients is 57.64 years.

3.5.2 Variables of Disease Activity

The following table presents several variables of disease activity. Since, for some patients, more than one questionnaire is entered into the SCQM per year, an average of the visit data was used for the analysis of the follow-up patients. In all tables and figures, the data are shown separately for inclusion and follow-up in 2007 and 2008. For the different scores the mean and the standard

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
Number of patients	431	389	2002	1996
Mean glob. NRS pat.	5.29	5.05	5.98	5.73
St.dev. glob. NRS pat.	2.52	2.51	2.59	2.66
mean DAS28(ESR)	4.14	4.16	3.17	3.07
St.dev. DAS28	1.42	1.45	1.26	1.25
mean RADAI	3.86	4.15	2.71	2.73
St.dev. RADAI	2.1	2.1	2.07	2.01
mean HAQ	0.93	0.91	0.85	0.82
St.dev. HAQ	0.71	0.67	0.74	0.73

Table 3: Disease activity at inclusion and at follow-up of patients with the indicated type of visit in 2007 and 2008. St.dev. stands for standard deviation. Mean glob. NRS pat. is the patients assessment of global health, on a numerical rating scale from 0 to 10 (0 meaning bad health and 10 excellent health). DAS28(ESR) is the Disease activity score, based on tender and swollen joint count and the erythrocyte sedimentation rate (scale 0 – 10, 10 being the maximal disease activity). The RADAI is the Rheumatoid Arthritis Disease Activity Index, which takes patient estimate of disease activity, of joint stiffness and pain in specified joint regions into account (scale 0 – 10, 10 being the highest disease activity). HAQ stands for Health Assessment Questionnaire, which measures physical disability (scale 0 – 3, 3 being the highest level of functional disability).

deviation are listed. The scores shown are the global health assessment by patient, the RADAI, DAS28 and HAQ (see caption Table 3 for explanation of these acronyms).

As shown in table 3 and figure 1, there is a difference between the groups of inclusion patients and follow-up patients. The RADAI and DAS28 scores show a higher disease activity for the patients when they were included in the SCQM data base. The same trend can be seen for the other relevant scores like the RADAI and DAS28. However, functional disability as measured by the mean HAQ score (Health Assessment Questionnaire) shows less variation, which is expected since this outcome measure is less sensitive to change. The DAS28 is a composite measure of the underlying inflammatory disease activity. The DAS28 can be classified into disease states, such as high, moderate or low disease activity. This interpretation is based on a classification system suggested by experienced rheumatologists (Van Gestel AM *et al*, Arthritis Rheum. 1998) and has shown to have predictive validity on development of joint destruction (Prevo MLL *et al*, Arthritis Rheum 1995). There are four categories: remission ($DAS28 \leq 2.6$), low disease activity ($2.6 < DAS28 \leq 3.2$), moderate disease activity ($3.2 < DAS28 \leq 5.1$) and high disease activity ($DAS28 > 5.1$). The DAS28 score has been widely adopted by researchers in rheumatology both in Europe and world-wide. Figure 2 presents the percentage of the patients for the four categories. About a quarter of patients have a high disease activity at inclusion in 2007 and 2008, whereas only about 10% of the follow-up patients belong to this category. Over a third of the follow-up patients, however, are in remission. This trend to lower disease activity at follow-up is probably related to

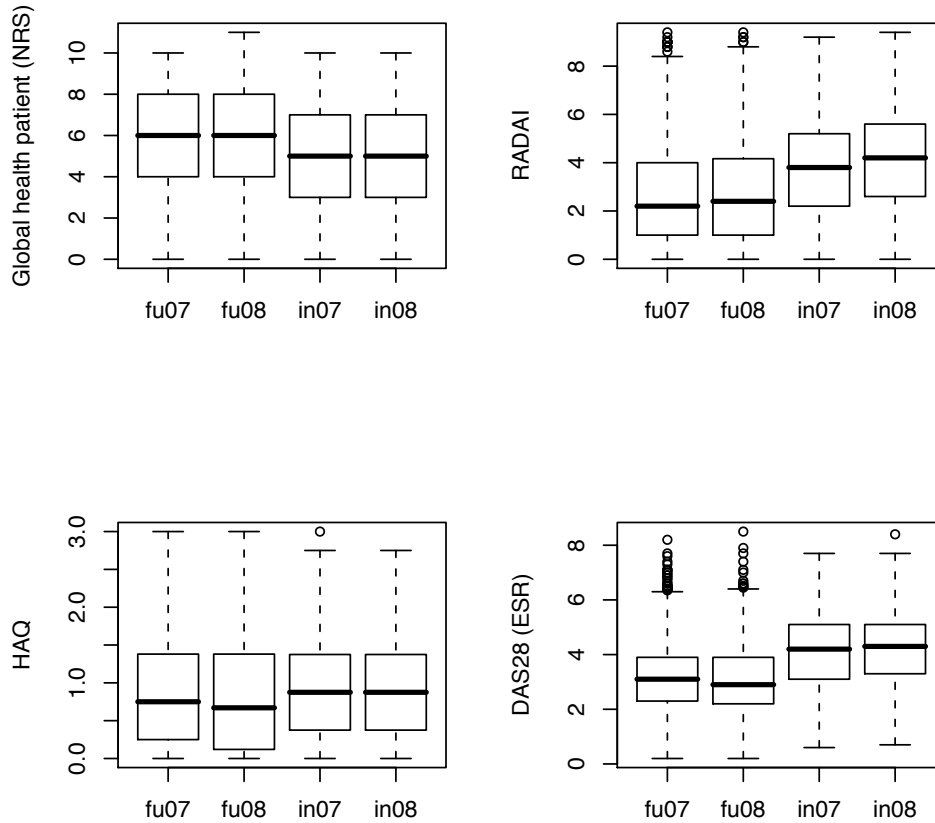


Figure 1: Box plots for the global health estimated by the patient, RADAI, HAQ and DAS28 (ESR). The box plots display median (fat black line in the box) and inter quartile range (range within the box). The data points that lie outside the whiskers are considered outliers. in07 and in08 stands for inclusion visits in 2007 and 2008 respectively and fu07 and fu08 stands for follow-up visit in 2007 and 2008 respectively.

the initiation of adequate anti-rheumatic therapy after inclusion into the registry.

3.5.3 Prescription of Disease Modifying Anti-rheumatic Drugs (DMARDs)

Disease Modifying Anti-rheumatic Drugs (DMARDs) are an important element in the treatment of rheumatoid arthritis. The most prescribed DMARD in active SCQM patients remains Methotrexate, followed by Leflunomide, Hydroxychloroquin and Sulfasalazine. More than half of patients who had a follow up visit in 2008 were under biologics treatment (Abatacept, Adalimumab, Etanercept, Infliximab, Rituximab).

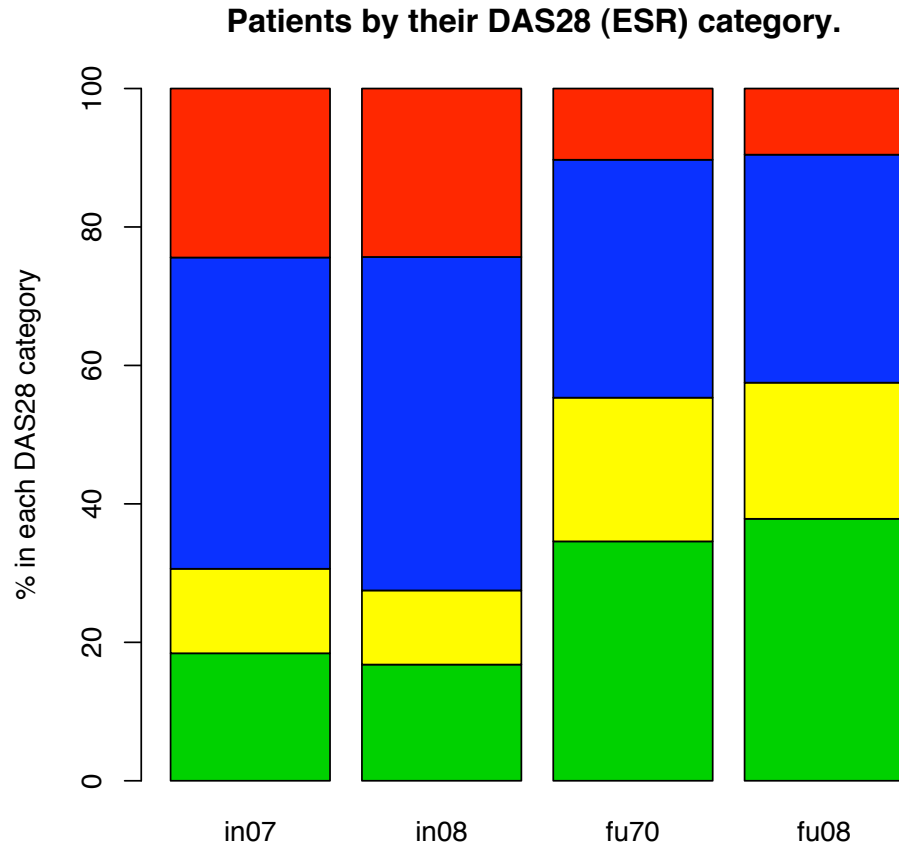


Figure 2: Percentage of patients in each of the DAS28 categories. In green is the percentage of patients in remission, in yellow those with low disease activity, in blue those with moderate disease activity and in red the percentage of patients with high disease activity. fu07 and fu08 stands for follow-up visit in 2007 and 2008 respectively, and in07 and in08 for inclusion visit in 2007 and 2008 respectively.

3.5.4 Surgeries

Both in the inclusion questionnaire as well as in the yearly control questionnaire, the number and type of surgeries are registered. In the inclusion questionnaire, all surgeries prior to inclusion are recorded, whereas in the yearly control questionnaire only new surgeries are captured. Therefore, the inclusion and follow-up groups can not be compared directly. As shown in table 4, for about one quarter of the patients, a surgery was reported to have occurred before inclusion. At follow-up visits, an operation was reported for 12-14% of the patients. Type and number of surgeries is listed below (table 5). Surgeries at hands, feet and knees were most common, followed by hip and shoulder surgeries.

For one patient with an inclusion visit in 2008, and another patient with a follow-up visit in 2007, a spine-straightening operation was reported. Since this is an atypical operation for patients with rheumatoid arthritis, it is not listed separately. This is the reason why the sum of the number of operations by type and the sum listed in the first line of the table do not add up in the column for inclusion 2008 and follow-up 2007.

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
number of patients	431	389	2002	1996
mean # of consultations	5.65	5.73	5	5.22
% patients w. hospital stay	6.73	5.14	7.54	4.61
# patients with OP(s)	62	83	201	229
total # OPs	98	118	239	276
OPs per pat.	0.23	0.3	0.12	0.14

Table 4: Number of consultations per year, and the number of hospital/rehabilitation clinic stay and operations in relation to rheumatoid arthritis reported in inclusion or follow-up visit in 2007 or 2008. In the inclusion, the rheumatologists are asked to list operations since the start of disease, and in yearly control visits only those in the past 12 months. Therefore the number of operations at inclusion and at follow-up are not directly comparable.

3.5.5 Unemployment due to rheumatoid arthritis

In the questionnaires for rheumatoid arthritis that were introduced in 2007, the patients are asked whether they had to reduce or quit their job due to their rheumatic disease and if yes, since when. In 2007 we still received a lot of old questionnaires, in which this question was not posed. Therefore, the number of 2007 and 2008 in table 6 are not comparable. The data displayed are patient reported only and uncleaned.

3.6 Errata yearly report 07

When one compares the values for the time from beginning of symptoms to diagnosis in this years Table 2 to that of last years yearly report, one can see that this value was much higher last year.

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
Total # of OPs	98	118	239	276
# hand OPs	18	30	45	65
# foot OPs	29	28	80	80
# spine OPs	11	11	18	20
# shoulder OPs	8	10	9	19
# knee OPs	18	17	48	51
# hip OPs	14	21	38	40
# other OPs	0	0	0	1

Table 5: Type of operations reported in 2007 and 2008, of patients who had an inclusion or follow-up visit in 2007 or 2008. In the inclusion, the rheumatologists are asked to list operations since the start of disease, and in yearly control visits only those in the past 12 months. Therefore the number of operations at inclusion and at follow-up are not directly comparable.

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
number of patients	431	389	2002	1996
% patients reduced job	(3.02)	11.31	(3.75)	12.98
median duration reduction (years)	7	1	6	7
% patients quit job	(3.94)	11.05	(4.35)	13.43
median duration (years)	2	1	7	7

Table 6: Percentage of patients who reduced or quit their job due to their rheumatic disease and median duration of reduction or interruption of work. The values for 2007 are indicated between brackets because only part of the questionnaires for 2007 were of the new type, that contained the questions on reduction or quitting of the job due to the rheumatic disease.

This is because I falsely asked for those cases where this duration was > 0 . There are, however, quite a few cases where this difference equals 0, because start of symptoms and diagnosis were within the same month.

In the RADAI calculations of the MsSQL database, the RADAI6, which is the average of the level of pain indicated separately for 16 joints by the patient, was not considered. In the calculation according to Fransen *et.al.*, RADAI6 is taken into account (J Fransen, G Stucki, J Twisk, A-M Chamot, J-C Gerster, T Langenegger, M Seitz, B A Michel, and the members of the Swiss Clinical Quality Management in Rheumatoid Arthritis (SCQM), *Ann Rheum Dis* 2003;62:624 – 629). In the online database, calculations were done according the description in this publication. Therefore the RADAI values in the yearly report 08 are not the same as that in yearly report 07.

4 Activity Report of the Ankylosing Spondylitis Cohort

4.1 Background information

The project on ankylosing spondylitis was started in 2004, supported by three members of the ASAS (ASsessmentS in Ankylosing Spondylitis) International Working Group, namely Prof. Dr. D. van der Heijde, Maastricht, president ASAS, Prof. Dr. M. Dougados, Paris, vice president ASAS, Prof. Dr. A. Boonen, Maastricht. The aims of the study are the collection of data on disease activity and functional parameters, the effectiveness of different therapies and socioeconomic issues of the disease. The collection of data on biologics and other medication allows the analysis of their benefit on the disease and socioeconomic consequences. Radiology represents an important element. A standardised conventional radiological instrument with four radiographs every two years is used.

4.2 Population

All patients in Switzerland with ankylosing spondylitis, independent of age, disease duration, severity and type of therapy can participate. It is not only a biologics registry, but a prospective observational cohort study. All Swiss rheumatologists are encouraged to contribute. At the end of May 2009, there were 1269 patients in the registry of ankylosing spondylitis with a total of 3035 visits. The median number of visits of all patients in the AS cohort was 2, and the maximum of the number of visits per patient is 10. The number of active patients in the AS cohort, with at least one entry in the SCQM between the 1st of January 2007 and the 31st of December 2008, was 1077.

4.3 Data collection

The questionnaires consist of an inclusion and a yearly control set. If relevant changes of disease activity or therapy occur, a questionnaire for an intermediate control should be filled in. All questionnaires are available in German and in French. Beside the use of internationally validated instruments, data on laboratory tests and four standardised radiographs every two years are collected.

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
number of patients	341	255	448	587
mean age (years)	39.75	41.81	43.03	42.47
Standard deviation	11.91	12.2	11.85	11.82
% Male	64.8	62	67.2	64.4
time sympt.-inclusion (months)	28	13	–	–
Inter-quartile range (months)	(3 - 121)	(3 - 95.5)	–	–

Table 7: Patient characteristics of inclusion and follow-up patients in 2007 and 2008

4.4 Results

4.4.1 Patient characteristics

Since 2005, the number of new inclusions in the AS registry have remained constant at around 300 per year. In 2007, we received 341 inclusions and 448 follow-up visit questionnaires (intermediate control or yearly control) in the data base. For 2008, so far 255 inclusion and 587 follow-up questionnaire-sets have flown into the data-base of ankylosing spondylitis.

As already mentioned, the four radiographs of pelvic, lateral-cervical spine and lateral and AP-lumbar spine are crucial to the AS registry. Patients with a radiographically confirmed diagnosis of AS can be used for further scientific analyses. Classification according to the pelvic radiograph is in process and will be integrated into the AS data base. For the analyses presented below, all active patients in the AS cohort were analyzed. This is a very heterogeneous group of patients, of which only a part will be classified as AS after the radiographic scoring by two experts.

About two thirds of the AS patients in the registry are men (see Table 7) and patients are on average about 41.81 and 42.47 years old (inclusion and follow-up patients for 2008 respectively). Between diagnosis and entry to the SCQM, a median of 28 and 13 months passed in 2007 and 2008 respectively. The range of the time passing between diagnosis and entry into the SCQM is very broad (interquartile range in 2008 (3 - 95.5)).

4.4.2 Variables of disease activity

The following table represents several disease activity and disability variables of the active patients in the AS registry.

4.4.3 Prescription of Disease Modifying Anti-rheumatic Drugs (DMARDs)

TNF-inhibitors are efficacious in the symptomatic treatment AS (Zochling J et al.. ASAS/EULAR recommendations for the management of ankylosing spondylitis Ann Rheum Dis 2006; 65(4): Epub 2005 Aug. 26.). The evidence for a reduction of structural progression by treatment with TNF-inhibitors, is, however, limited (Baraliakos X et al.. Radiographic progression in patients with ankylosing spondylitis after 4 yrs of treatment with the anti-TNF-alpha antibody infliximab. Rheumatology 2007; 46(9): 1450 – 1553.).

In the SCQM registry, less than 50% of patients are under anti-TNF treatment. Of the 587 patients for whom a follow-up questionnaire was available for 2008, 125 were treated with infliximab, 141 with etanercept and 143 with adalimumab.

4.4.4 Surgeries

In the AS registry, doctors were asked to list operations related to the disease since the start of disease (at inclusion) or in the last 12 months (at yearly control visit). Table 9 lists the number of patients that had an surgery and the total number of surgeries. Table 10 lists the number of operations by type.

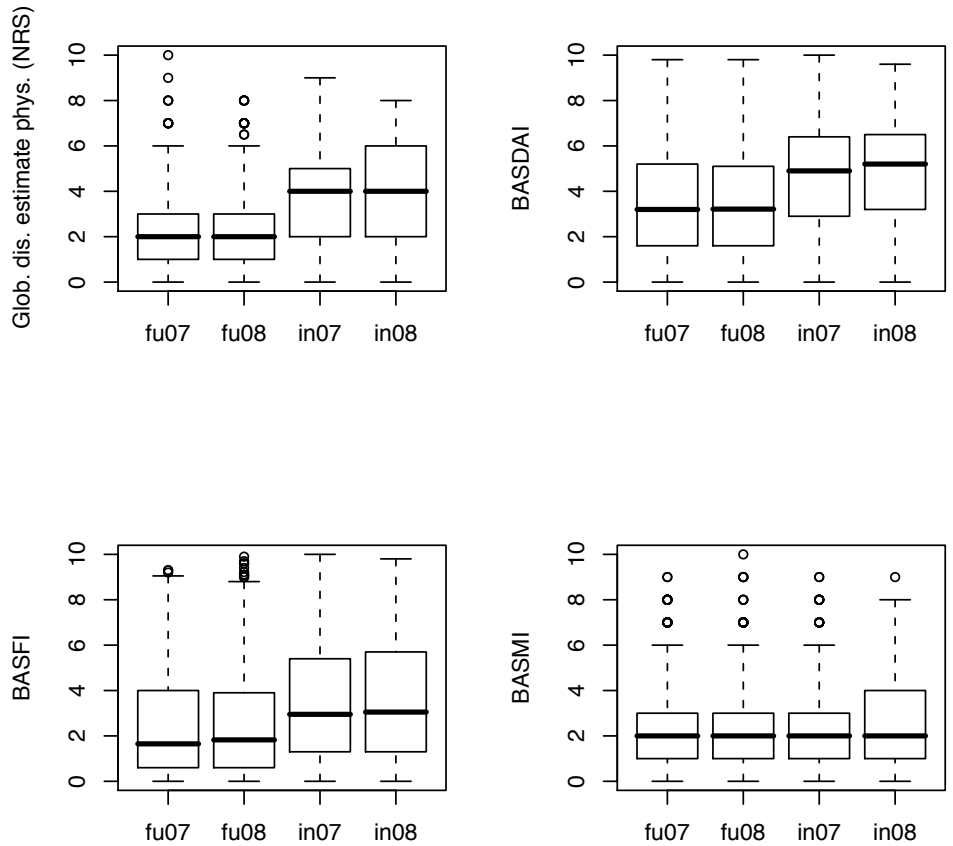


Figure 3: Box plots for the global disease activity estimated by the physician (glob. dis. estimate phys.), BASDAI, BASFI and BASMI. (For a description of these acronyms see table 8). The box plots display median (fat black line in the box) and inter quartile range (range within the box). The data points that lie outside the whiskers are considered outliers. in07 and in08 stands for patients with an inclusion visit in 2007 and 2008 respectively and fu07 and fu08 stands for follow-up visit in 2007 and 2008 respectively.

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
number of patients	341	255	448	587
mean glob. NRS pat.	5.28	5.59	3.62	3.62
St.dev. glob NRS pat.	2.71	2.8	2.51	2.57
mean glob. NRS phys.	3.75	3.9	2.1	2.15
St.dev. glob NRS phys.	2.2	2.14	1.78	1.8
mean BASDAI	4.73	4.93	3.55	3.51
St.dev. BASDAI	2.26	2.3	2.31	2.22
mean BASFI	3.48	3.55	2.59	2.53
St.dev. BASFI	2.55	2.59	2.48	2.37
mean BASMI	2.24	2.4	2.31	2.17
St.dev. BASMI	2.06	2.07	2.16	2.05

Table 8: Disease activity at inclusion and at follow-up of patients with the indicated type of visit in 2007 and 2008. St.dev. stands for standard deviation. Glob. NRS pat. and glob. NRS phys. stand for the global estimate of disease activity on a numerical rating scale by the patient and the physician respectively. BASDAI stands for Bath Ankylosing Spondylitis Disease Activity Index, BASFI for the Bath Ankylosing Spondylitis Functionality Index and BASMI for the Bath Ankylosing Spondylitis Metrology Index. All of these indexes are on a scale from 0 – 10, 0 being no disease activity and 10 maximal disease activity.

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
number of patients	341	255	448	587
% patients w. hospital stay	15.84	15.29	6.47	5.28
# patients with OPs	34	34	20	21
total # OPs	38	39	22	21
OPs per pat.	0.11	0.15	0.05	0.04

Table 9: Hospital or rehabilitation clinic stay in relation to the ankylosing spondylitis arthritis and operations reported in inclusion or follow-up visits in 2007 or 2008. In the inclusion questionnaires of ankylosing spondylitis, the rheumatologists are asked to list hospital stay and operations since the start of disease, whereas in yearly control visits only over the past 12 months. Therefore the number of patients with a hospital stay and the number of operations at inclusion and at follow-up are not directly comparable.

4.4.5 Unemployment due to ankylosing spondylitis

Patients are asked if, and if so, since what year, they have had to reduce or quit their job due to their rheumatic disease. The data displayed are patient reported only and uncleaned.

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
Total # of OPs	38	39	22	21
# SS OPs	2	4	4	1
# shoulder OPs	7	3	3	0
# knee OPs	1	3	2	2
# hip OPs	7	5	6	6
# other OPs	21	24	7	12

Table 10: Type of operations reported in inclusion or follow-up visits in 2007 or 2008. In the inclusion questionnaires of ankylosing spondylitis, the rheumatologists are asked to list hospital stay and operations since the start of disease, whereas in yearly control visits only over the past 12 months. Therefore the number of patients with a hospital stay and the number of operations at inclusion and at follow-up are not directly comparable. SS OP is spine straightening operation.

	Inclusion 07	Inclusion 08	Follow-up 07	Follow-up 08
number of patients	341	255	448	587
% patients reduced job	16.72	12.16	13.84	13.8
median duration reduction (years)	3	4	6	5
% patients quit job	13.2	16.47	9.38	8.18
median duration (years)	4	4	4.5	6

Table 11: Percentage of patients who reduced or quit their job due to their rheumatic disease and median duration of reduction or interruption of work.

5 Activity Report of the Psoriatic Arthritis Cohort

5.1 Background information

The project on psoriatic arthritis (PsA) was started at the end of 2004, mainly developed by Dr. Adrian Forster, at this time with the University Hospital Zürich, now Thurgauer Klinik St. Katharinen, Diessenhofen. In 2005 the PsA Commission was established. PD Dr. Burkhard Möller, Inselspital Bern, agreed to take the chair of the commission. In order to improve the cooperation with the dermatologists, a representative of them is a member of the commission. The aims of the register are the collection of data on disease activity and functional parameters, the effectiveness of different therapies and socioeconomic issues of the disease. Important aspects like involvement of the skin and osteoporosis are also considered. Unlike the other two registries radiographic information is not yet collected.

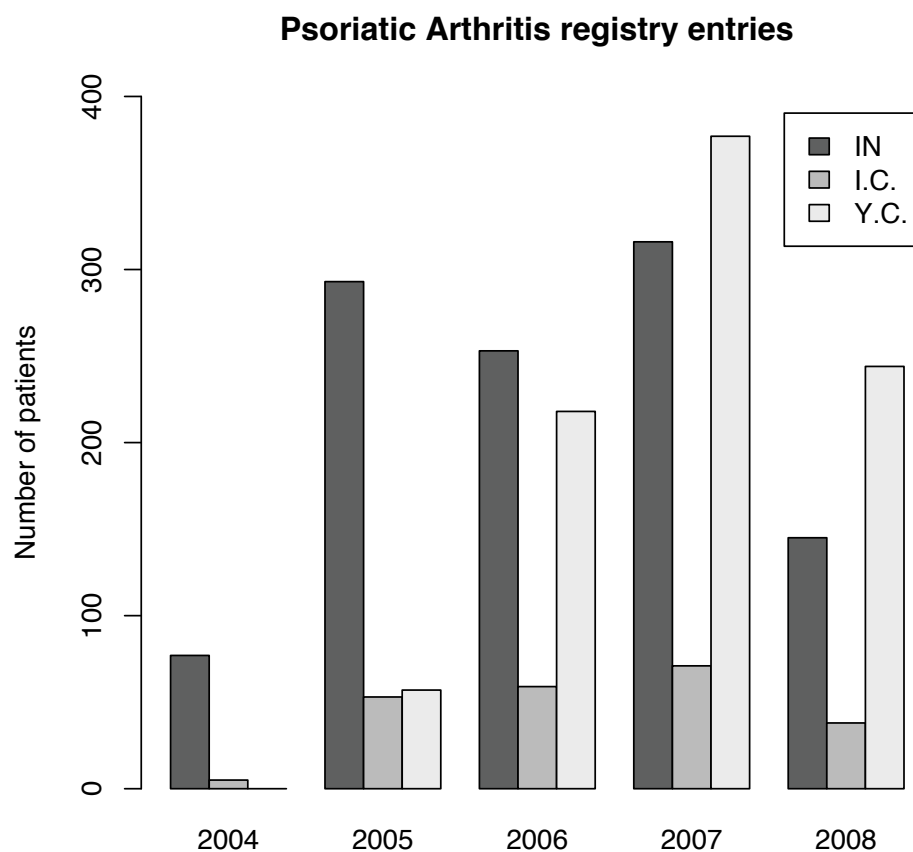


Figure 4: The number of inclusion (IN), intermediate control (I.C.) and yearly control (Y.C.) visits for psoriatic arthritis from 2004 to 2008.

5.2 Population

All patients with psoriatic arthritis in Switzerland, independent of age, disease duration, severity and type of therapy can participate. It is a population based prospective observational study.

5.3 Data collection

A clinical examination and the collection of blood samples are included during initial, intermediate control and annual control visits. Patients are also asked to complete a questionnaire. All collected data (physician and patient) is communicated to the SCQM Office for evaluation. The questionnaires are available in German and French.

5.4 State of the project

90 patients were included in the first year after starting the PsA registry. The number of inclusions and follow-up entries in the SCQM has grown steadily since 2005. Approximately half of the PsA patients are under treatment with a biologic. The PsA registry has also been developed in the online database. New data can be entered online directly. We are currently entering the data that have been collected since 2005 into the online database manually.

5.5 Future of the registry for psoriatic arthritis

During the development of the online database, the questionnaires of PsA have been revised. These revised questionnaires are available online and in paper form.

In the following months, the PsA data will be entered into the online database, and by the end of 2009, an x-ray database for PsA is planned to be in place.

6 Patrons and sponsors

6.1 Patrons



6.2 Sponsors



- Fondation Jean & Linette Warnery
- Rheumastiftung Zürich



SCHWEIZERISCHER VEREIN BALGRIST
TRÄGER DER



7 Annual Accounts

7.1 Auditor's Report



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Bericht der Revisionsstelle zur eingeschränkten Revision an den Stiftungsrat der

SCQM Foundation, Zürich

Als Revisionsstelle haben wir die Jahresrechnung (Bilanz, Betriebsrechnung und Anhang) der SCQM Foundation für das am 31. Dezember 2008 abgeschlossene Geschäftsjahr geprüft.

Für die Jahresrechnung ist der Stiftungsrat verantwortlich, während unsere Aufgabe darin besteht, diese Jahresrechnung zu prüfen. Wir bestätigen, dass wir die gesetzlichen Anforderungen hinsichtlich Zulassung und Unabhängigkeit erfüllen.

Unsere Revision erfolgte nach dem Schweizer Standard zur Eingeschränkten Revision. Danach ist diese Revision so zu planen und durchzuführen, dass wesentliche Fehlaussagen in der Jahresrechnung erkannt werden. Eine eingeschränkte Revision umfasst hauptsächlich Befragungen und analytische Prüfungshandlungen sowie den Umständen angemessene Detailprüfungen der beim geprüften Unternehmen vorhandenen Unterlagen. Dagegen sind Prüfungen der betrieblichen Abläufe und des internen Kontrollsystems sowie Befragungen und weitere Prüfungshandlungen zur Aufdeckung deliktischer Handlungen oder anderer Gesetzesverstösse nicht Bestandteil dieser Revision.

Bei unserer Revision sind wir nicht auf Sachverhalte gestossen, aus denen wir schliessen müssten, dass die Jahresrechnung nicht Gesetz, Stiftungsurkunde und Reglement entspricht.

KPMG AG

Hans Knobel
Zugelassener Revisionsexperte
Leitender Revisor

Martin Hemmi

Zürich, 14. April 2009

Beilage:

- Jahresrechnung (Bilanz, Betriebsrechnung und Anhang)

7.2 Balance

SCQM Foundation, Zürich

Bilanz per 31. Dezember	Anmerkung	2008	2007
		CHF	CHF
AKTIVEN			
Umlaufvermögen			
Flüssige Mittel		407,916.54	235,971.65
Debitoren		48,420.00	0.00
Andere Forderungen		13,874.65	16,953.95
Aktive Rechnungsabgrenzung		0.00	9,364.90
		<u>470,211.19</u>	<u>262,290.50</u>
Anlagevermögen			
Sachanlagen			
- EDV	2	20,841.00	14,721.25
- Datenbank "Bechterew"		0.00	24,344.93
- Onlinedatenbank	2	78,576.90	0.00
		<u>99,417.90</u>	<u>39,066.18</u>
		<u>569,629.09</u>	<u>301,356.68</u>
PASSIVEN			
Fremdkapital			
Verbindlichkeiten gegenüber Dritten		26,705.93	84,077.81
Übrige kurzfristige Verbindlichkeiten		53,543.36	38,642.35
Darlehen Klinik Balgrist	3	230,000.00	40,000.00
		<u>310,249.29</u>	<u>162,720.16</u>
Fonds für Online Datenbank	4	<u>50,607.05</u>	<u>0.00</u>
Stiftungskapital			
Stiftungskapital		80,000.00	80,000.00
Bilanzsaldo			
Gewinnvortrag		58,636.52	47,544.01
Jahresgewinn		70,136.23	11,092.51
		<u>208,772.75</u>	<u>138,636.52</u>
		<u>569,629.09</u>	<u>301,356.68</u>

7.3 Income Statement

SCQM Foundation, Zürich

Betriebsrechnung	Anmerkung	2008	2007
		CHF	CHF
ERTRAG			
Erlös aus Sponsoring		540,000.00	630,000.00
Erlös aus zus. Dienstleistungen		0.00	500.00
Spenden	4	186,000.00	5,000.00
Übriger Ertrag		1,500.00	2,070.00
		<u>727,500.00</u>	<u>637,570.00</u>
AUFWAND			
Personalaufwand		-383,909.53	-422,977.70
Raumaufwand		-49,863.25	-25,611.23
Verwaltungs- und Informatikaufwand		-109,804.52	-110,621.71
Übriger Aufwand		-15,168.92	-9,816.00
Abschreibungen		-48,429.85	-57,338.35
		<u>120,323.93</u>	<u>11,205.01</u>
Ergebnis vor Zinsen			
Finanzertrag		1,130.05	274.60
Finanzaufwand		<u>-710.70</u>	<u>-387.10</u>
Ergebnis vor Fondsbuchungen		120,743.28	11,092.51
Zuweisung an Fonds	4	-150,000.00	0.00
Verwendung aus Fonds	4	99,392.95	0.00
Jahresgewinn		<u><u>70,136.23</u></u>	<u><u>11,092.51</u></u>

7.4 Annexe

SCQM Foundation, Zürich

Anhang der Jahresrechnung 2008

1 Gründung und Stiftungszweck

Die SCQM Foundation (Swiss Clinical Quality Management in Rheumatoid Arthritis) mit Sitz in Zürich, wurde gemäss der Stiftungsurkunde per 1. Oktober 2003 notariell beurkundet und per 12. Februar 2004 ins Handelsregister eingetragen.

Im Geschäftsjahr 2008 änderte die Gesellschaft ihren Namen wie folgt:

SCQM Foundation (Swiss Clinical Quality Management in Rheumatic Diseases)

Zweck der Stiftung ist:

Die Stiftung will im Bereich der Rheumatologie eine unabhängige, von lokalen, regionalen und persönlichen Interessen freie Forschungsplattform errichten und betreiben. Sie verfolgt weder Erwerbs- noch Selbsthilfzwecke. Die Stiftung bezweckt insbesondere die kontinuierliche Verbesserung der Qualität der Behandlung der rheumatoiden Arthritis mittels eines feedback-gestützten Messsystems.

2 Brandversicherungswert EDV

2008

2007

CHF

CHF

Feuer / Elementar / Erweiterte Deckung

230,000

100,000

3 Darlehen der Klinik Balgrist

Es bestehen zwei Passivdarlehen der Klinik Balgrist.

Darlehen im Betrag von CHF 30,000 aus den Vorjahren unbefristet, mit einer Kündigungsfrist von sechs Monaten, jeweils auf Ende des Kalenderjahres kündbar.

Darlehen im Betrag von CHF 200,000 für die Vorfinanzierung der Onlinedatenbank. CHF 50,000 rückzahlbar bis 31. Dezember 2009 und CHF 150,000 rückzahlbar bis 31. Dezember 2010. Die Darlehen wurden zinslos gewährt.

4 Fonds für Online Datenbank

Im Geschäftsjahr 2008 erfolgte eine zweckgebundenen Spendenzahlung im Umfang von CHF 150,000 der Schweizerischen Gesellschaft für Rheumatologie zur Finanzierung der Onlinedatenbank.

5 Risikobeurteilung

Der Stiftungsrat hat periodisch ausreichende Risikobeurteilungen vorgenommen und allfällige sich daraus ergebende Massnahmen eingeleitet, um zu gewährleisten, dass das Risiko einer wesentlichen Falschaussage in der Rechnungslegung als klein einzustufen ist. Bei der Bilanzierung und Bewertung trifft der Stiftungsrat Einschätzungen und Annahmen bezüglich der Zukunft. Insgesamt wurden im abgelaufenen Geschäftsjahr keine Risiken identifiziert, die zu einer wesentlichen Korrektur der im Jahresabschluss dargestellten Vermögens-, Finanz- und Ertragslage der Stiftung führen könnten.

8 The Swiss Clinical Quality Management (SCQM) Foundation in Rheumatic Diseases

8.1 Background information

First attempts to initiate the start up of a data base for rheumatoid arthritis were undertaken back in 1995. The subsequent collection of regular patient follow-up data was started in 1996. The project started at the University Hospital of Zürich, supported by Dutch colleagues. The idea was to put a comprehensive quality management into clinical practice. Prof. Dr. Gerold Stucki together with Dr. Thomas Langenegger, Dr. Adrian Forster and Prof. Dr. Beat Michel were the initiators of the project. The project expanded more and more in the past years. The need for a better organizational and political framework arose. In summer 2003 the Swiss Clinical Quality Management FOUNDATION was established under the umbrella of the Swiss Society for Rheumatology (Schweizerische Gesellschaft für Rheumatologie, SGR). The founders of this non-profit organization comprise 23 rheumatological clinics and two societies. The list of the founding hospitals is shown in section 8.7.

8.2 The SCQM Board

The overall authority of SCQM is the FOUNDATION Board. It is composed of five to seven members including a president and a vice-president. At least two members of the Board have to be active members of the SGR Board of directors. In 2005 the SCQM Board agreed that patrons (the main sponsors of SCQM) will have a temporary seat for one year in rotation on the Board. In 2008 the patrons were represented by Miss Lucia Suter of the company Essex. The members of the SCQM Board are (as of December 2008):

- Dr. Hans A. Schwarz (President), Emeritus Head of Rheumatology Dep. Bethesdaspital, Basel
- Prof. Dr. Cem Gabay (Vice-President), Hôpitaux Universitaires de Genève, Geneva
- Ms Gisela Dalvit, Emeritus Head of the Swiss League against Rheumatism
- Dr. Adrian Forster, Thurgauer Klinik St. Katharinental, Diessenhofen
- Prof. Dr. Paul Hasler, Kantonsspital Aarau, Aarau
- Prof. Dr. Rudolph Kissling, Universitätsklinik Balgrist, Zürich
- Dr. Marie-Josèphe Sauvain, medical specialist FMH, Fribourg

8.3 The Executive Committee

In 2006 an Executive Committee was set up, this group was elected out of the members of the SCQM Board. The aim of the establishment was to reduce the workload and to prepare decisions for the Board members.

- Dr. Hans A. Schwarz (President), Emeritus Head of Rheumatology Dep. Bethesdaspital, Basel
- Ms Gisela Dalvit, Emeritus Head of the Swiss League against Rheumatism
- Dr. Adrian Forster, Thurgauer Klinik St. Katharinental, Diessenhofen
- Prof. Dr. Rudolph Kissling, Universitätsklinik Balgrist, Zürich
- Sabine von Känel, Executive Secretary
- Dr. Almut Scherer, Scientific Manager

8.4 The Scientific Committees

In order to be able to concentrate more efficiently on strategic issues, the SCQM Board decided to establish a scientific commission for each register. Since the commissions will mainly deal with the scientific aspects of the register, their members should be experts in the field of the respective register. It is recommended that at least one member of the commission should be a private practitioner in order to bring in the relevant inputs of a private practice. The chairmen of the commissions also participate in the SCQM Board meetings to assure a link between strategic and operational level of the SCQM Foundation.

RA Commission

- Dr. Axel Finckh (Chairman), Hôpitaux Universitaires de Genève
- Dr. Ines von Mühlengen, medical specialist FMH, Basel
- Dr. Jean Dudler, Centre Hospitalier Universitaire Vaudois, Lausanne
- PD Dr. Diego Kyburz, Universitätsspital Zürich

AS Commission

- Dr. Ulrich Weber (Chairman), Universitätsklinik Balgrist, Zürich
- Dr. Pascale Exer, medical specialist FMH, Basel
- Dr. Jürg Bernhard, Bürgerspital Solothurn

- Dr. Adrian Ciurea, Universitätsspital Zürich
- Dr. Giorgio Tamborini, Universitätsspital Zürich

PsA Commission

- PD Dr. Burkhard Möller (Chairman), Inselspital, Bern
- Dr. Jean Dudler, Centre Hospitalier Universitaire Vaudois, Lausanne
- Dr. Bettina Weiss, Bethesda Spital, Basel
- Prof. Dr. Nikhil Yawalkar (Dermatologist), Inselspital, Bern

8.5 The SCQM Office

- Sabine von Känel, executive Secretary
- Almut Scherer, scientific manager (from 04.2008)
- Claudia Cutler, assistant for Administration, Communication and PsA (until 04.2008)
- Susanne Frieser, assistant for Administration and PsA (from 04.2008)
- Jacqueline Hirt, assistant for AS
- Rowena Laue, data management and statistics (until 10.2008)
- Marion Täsch Furger, assistant RA X-rays scoring (until 04.2008)
- Mirta Viviani, assistant RA X-rays scoring (from 04.2008)
- Heinz Wyrsh, assistant for RA

8.6 The SCQM Organigramm

The Organigramm of the SCQM Foundation is displayed graphically in Figure 5. The SCQM office team reports to the Board of the Foundation. Operative issues are discussed first within the Executive Board, which consists of representatives of the Board of the Foundation and of the scientific and general manager of the SCQM office. Important points are presented to the Board of the Foundation at the board meetings. The SCQM office team is in regular contact with the members of the Scientific Commissions.

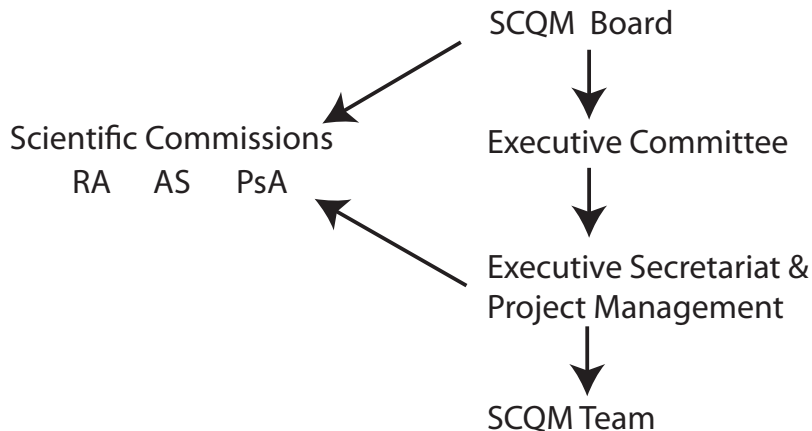


Figure 5: Organigramm of the SCQM.

8.7 List of SCQM Founders

- aarReha, Schinznach Bad
- Abteilung für Rheumatologie und Rehabilitation, Kantonsspital St. Gallen
- Abteilung für Rheumatologie/Rehabilitation, Kantonsspital Schaffhausen
- Hôpitaux Universitaires de Genève, Div. de Rhumatologie, Genève
- Hôpital cantonal de Fribourg, Service de Rhumatologie, Fribourg
- Klinik Adelheid AG, Unterägeri
- Klinik für Rheumatologie und Klinische Immunologie/Allergologie, Inselspital Bern
- Klinik für Rheumatologie und Rehabilitation des Bewegungsapparates, Klinik Valens
- Klinik für Rheumatologie und Rehabilitation, Bethesda Spital, Basel
- Klinik für Rheumatologie und Rehabilitation, Stadtspital Triemli, Zürich
- Klinik Schloss Mammern AG
- Rehabilitationszentrum Leukerbad AG
- Rehabilitationszentrum Bürgerspital Solothurn
- RehaClinic Zurzach

- Rehaklinik Rheinfelden
- Rheumaklinik Kantonsspital Luzern
- Rheumaklinik Kantonsspital Winterthur
- Rheumaklinik und Institut für Physikalische Medizin und Rehabilitation, Kantonsspital Aarau
- Rheumaklinik und Institut für Physikalische Medizin, Universitätsspital Zürich
- Rheumatologische Universitätsklinik, Felix Platter-Spital, Basel
- Service de Rhumatologie, Médecine Physique et Réadaptation, Centre Hospitalier Universitaire Vaudois, Lausanne
- Thurgauer Klinik St. Katharinental, Diessenhofen
- Universitätsklinik Balgrist, Abteilung für Rheumatologie, Zürich
- Rheumaliga Schweiz, RLS
- Schweizerische Gesellschaft für Rheumatologie, SGR

9 Publications

9.1 2007

- Finckh A , Dehler S, Costenbader K, Gabay C, on behalf of the SCQM-RA. Cigarette smoking and radiographic progression in rheumatoid arthritis. *Annals of the Rheumatic Diseases* 2007; 66; 1066-1071.
- Finckh A, Ciurea A, Brulhart L, Revaz S, Möller B, Dehler S, Kyburz D, Dudler J, Gabay C, on behalf of the SCQM-RA. Rituximab may be more effective than switching to an alternative anti-TNF agent in RA patients with inadequate response to anti-TNF agents. *Arthritis and Rheumatism* 2007; May 2007; 56(5), 1417-23.
- Genevay S*, Finckh A*, Ciurea A, Chamot AM, Kyburz D, Gabay C, for the physician of the SCQM-RA (* Authors have equally contributed). Tolerance and effectiveness of anti-TNF- α therapies in elderly patients with rheumatoid arthritis. A population based cohort study. *Arthritis and Rheumatism* 2007 Apr 30; 57(4):679-685.

9.2 2008

The following manuscripts on SCQM data were finalized, submitted and accepted by the most highly rated journals in the field of rheumatology in 2008, but have been or will be published in 2009.

- Finckh A, Ciurea A, Brulhart L, Möller B, Walker UA, Courvoisier D, Kyburz D, Dudler J, Gabay C. Which Subgroup of Rheumatoid Arthritis Patients Benefits From Switching to Rituximab Versus Alternative Anti-TNF Agents After Previous Failure to Anti-TNF Agent? *Annals of the Rheumatic Diseases* May 2009, Epub ahead of print
- Pan SM, Dehler S, Ciurea A, Ziswiler HR, Gabay C, Finckh A, on behalf of the Swiss Clinical Quality Management Physicians. Comparison of drug retention rates and causes of drug discontinuation between anti-tumor necrosis factor agents in rheumatoid arthritis. *Arthritis and Rheumatism*, 2009 May 15;61(5):560 – 8.
- Finckh A, Dehler S, Gabay C, on behalf of the Swiss Clinical Quality Management Physicians. The effectiveness of leflunomide as a co-therapy of tumour necrosis factor inhibitors in rheumatoid arthritis: a population-based study. *Annals of the Rheumatic Diseases*, 2009 Jan;68(1):33 – 9

10 Acknowledgements

Julia Braun of the Institute für Sozial und Preventivmedizin (ISPM) helped in the set-up and further use of the Sweave used to generate this document. (Sweave is a tool that allows you to combine L^AT_EX and R). Robert Carnecky helped write and automatize the data queries. Dr. med. Axel Finckh, Dr. med. Burkhard Möller, Dr. med. Ulrich Weber and Sabine von Känel proofread the yearly report. The help of these persons is greatly appreciated.



CONTACT INFORMATION

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