SCQM FOUNDATION
Swiss **C**linical **Q**uality **M**anagement
in Rheumatic Diseases

The SCQM data can be the basis for your next study.
The SCQM Foundation welcomes research on its long-term, Swiss-wide, data on patients with inflammatory rheumatic diseases.
The regulations below describe access to the data and the rules concerning publication.

Definitions:
1. Applicant: The head of studies or the director of studies.

Rules of research and co-operation

1. Access to data
In principle, any rheumatologist who is actively involved with the SCQM can submit study inquiries.

Conditions for study requests:

Studies with clinical data and patient data:
Entry of visit data from at least 5 patients in the past 2 years prior to study request.

Studies with clinical data, patient data and SONAR scores:
Entry of visit data from at least 5 patients in the past 2 years and a total of 30 SONAR scores prior to study request.

Studies with clinical data, patient data and biosamples:
Entry of visit data from at least 5 patients in the past 2 years and biosamples from at least 10 patients prior to study request.

The applicant must describe the purpose of the study and accept the provisions of this regulation.

We welcome the use of data for international collaborative studies. Analyses should be performed by the Swiss study applicant or internally by SCQM statisticians. The required data may be sent to the head of the international project in exceptional, justified cases.

2. Form of the data provided and ownership of the data
The SCQM supplies coded research data exclusively for study purposes.
1. A subsequent completion of the data relevant for the study (missing data) can be carried out internally by the SCQM on behalf of the applicant.
2. An extension to the list of questions needed for the study must be submitted to the SCQM foundation advisory board and approved by them before the study enquiry. The ownership of this additional data lies in principle with the SCQM. The resulting costs must be carried by the applicant.

3. Ethics
1. With the inception of the Human Research Act on 1 January 2014, any study with SCQM data requires an ethics approval. A copy of the ethics approval must be sent to the SCQM no later than before first submission of the study results as

an abstract or manuscript. In projects involving biosamples, the ethics approval must be obtained **before** the biosamples are supplied.

4. Approval procedure for data release

1. The request form for the use of SCQM data is to be filled out and submitted to the SCQM office. The request form can be ordered from the SCQM or downloaded from its website:
   http://www.scqm.ch/research/request-form-scqm-data.
2. The study proposal is checked for completeness by the SCQM office and then sent to the members of the scientific committee of the relevant cohort for evaluation.
   The Scientific Advisory Board of the Biobank is responsible for the evaluation of study requests with material from the SCQM Biobank. *Guidelines for the use of samples from the SCQM Biobank are included in Appendix I of these rules.*
   The request will be evaluated within 15 working days.
3. The study proposal and comments from the persons mentioned under 4.2 are summarized and sent by the SCQM to the foundation advisory board for evaluation.
4. The Foundation Board shall finally decide by circular letter (e-mail) on the study requests. In the absence of a **dissenting vote** of a Foundation Board member, the request will be approved after 15 working days.
   i. In the event of one or more scientifically justified dissenting votes of the Foundation Board, the applicant shall be given an opportunity to address the issues raised.
   ii. The Foundation Board shall thereafter agree on the circular letter whether the request is to be accepted in the context of the suggested changes by the applicant. With a relative majority the request shall be considered as accepted.

   The SCQM office shall inform the applicant immediately of the acceptance or refusal of the study request. In the latter case the office shall in addition inform the applicant of the reason for the refusal.
5. Until their publication by the Foundation Board, all documents are to be ***treated confidentially*** by all persons who have access to them in accordance with articles 4.2. and 4.4.
6. Following acceptance of the study request the SCQM office shall make the necessary research data available to the applicant. The costs of making the data available are charged to the applicant in accordance with articles 6.1 and 6.2.
   The applicant shall be responsible for the security of the data made available to him.
   i. In the majority of cases, the SCQM provides a custom-made data-set for the approved study.
   ii. In certain cases, the SCQM may send the applicant a dump of the raw research database data.

5. Participation in studies

The criteria for authorship are listed in article 9.

1. Members of the scientific committees of the SCQM can participate, after consultation with and agreement of the applicant, in studies with SCQM data.
2. Pinboard for studies: The SCQM website provides a pinboard for approved study projects. All Swiss study projects with SCQM data are displayed there for 2 months. During this time, any interested party who wishes to participate in the study can notify the applicant and/or the SCQM office.
3. The applicant shall decide on a possible co-operation with the persons who have expressed an interest in participating in the study. In the event of disagreement, a solution may be sought through the SCQM Foundation Board.

6. Fees

1. The expenditure on specific data inquiries or processing by SCQM is charged as follows: CHF 150.00/h (VAT excl.) for actively involved rheumatologists[1] as well as for main sponsors. CHF 250.00/h (VAT excl.) for all other clients.
2. For each study project, actively involved applicants are entitled to 10 hours of support (data extraction and statistical evaluations) *free of charge,* performed by qualified SCQM staff. Commencing with the 11th hour, charges for a study project will be levied in accordance with the charges set out in article 6.1.
3. Quotations will be provided on request.

7. Amendments to the study protocol

1. In the event of a substantial change to the study request, the applicant must submit an amendment study protocol, indicating the changes. This is submitted to the head of the appropriate scientific committee(s) and the Foundation Board. The decision-making process on the supplement submitted follows the process described in article 4.4, with a decision period of 5 working days.

8. Abstracts & publications

Inspection by the SCQM: Before submitting abstracts or manuscripts (hereinafter: "the work") for publication these must be submitted to the SCQM. The applicant shall send the work to the SCQM office, where a member of staff will check whether the work is in line with the underlying research request.

The work is passed on for information to the Foundation Board and the members of the scientific committees.

The examination of the documents is confirmed by means of signature by the scientific management of the SCQM on the research request form.
The periods for the submission of the material to be published:

i. Abstracts for congresses: at least 5 working days before submission
ii. Manuscripts for publications: at least 10 working days before submission

In the event of a relevant deviation of the work from the submitted research request the scientific management of the SCQM shall consult the Foundation Board and the head of the relevant scientific committee. The Foundation Board shall thereafter decide by circular letter (e-mail) and a relative majority whether the suggested work may be submitted for publication.

Within six months after publication of a manuscript, the applicant sends the SCQM office about **5 slides with the most important conclusions of the study and a copyright confirmation** (the SCQM provides a template for the slides). These slides will be made available to the rheumatologists working with the SCQM on the log-in-protected SCQM online database and can be used for lectures (mandatory indication of source).

9. Authorship rule

(Reference: Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (www.icmje.org))

1. **Authorship and participants:** Persons who fulfil all of the following criteria qualify as authors:
   i. Make a substantial contribution to the concept, study design, data acquisition or analysis and interpretation of the data
   ii. Draft or critical review of the manuscript
   iii. Agreement for the publication version of the work

   Procurement of finances, data gathering or general supervision of the research group alone do not qualify for authorship.

2. **Inclusion in the acknowledgments:**
    i. Provision of technical, editorial or other assistance justifies a mention in the acknowledgements.
    ii. Persons, who contributed substantially to the article, but who do not qualify for authorship, are listed as "Clinical Investigators" or "Participating Investigators". Their contribution should be specified:
        e.g. - worked as a scientific adviser
        - collected data
        - commented critically on the study design
        - cared for study patients, etc.

    These persons must give their written consent to be listed in the article.
3. **Mention of the SCQM in studies:** The SCQM will be mentioned as follows:
    i. If possible in the author list: "*on behalf of the participating physicians of the Swiss Clinical Quality Management in Rheumatic Diseases*",
    ii. at least, however, in the acknowledgements: "… *A list of rheumatology offices and hospitals that are contributing to the SCQM registries can be found on www.scqm.ch/institutions*". This website contains a list of physicians with the hospitals and practices who collect patient data for the SCQM. The list is arranged according to the number of patients with data entries within the last 2 years.
    iii. Additionally, at a suitable place, e.g. under "Financing" or under "Acknowledgements" it should be stated that: *"The SCQM is financially supported by pharmaceutical industries and donors. A list of financial supporters can be found on www.scqm.ch/sponsors."*

10. Publication of the studies on the SCQM website

Ongoing study projects and peer-reviewed publications are published on the SCQM website under <<Research>> as follows:

1. **Pinboard:** Granted study projects. Publication for 2 months. Interested researchers can apply to collaborate in the study project.
2. **Current study projects:** Titles of ongoing projects are listed.
3. **Publications:** Study titles and authors are listed. Abstracts can be consulted via a link (pubmed).

11. Period of validity

If the study duration indicated in the study request is exceeded, the SCQM Foundation Board may require a request for modification of the study protocol from the applicant.

12. Scope and publication of the rules

1. These rules are exclusively valid for study applications.
2. The rules must be published on the SCQM website.

Updated version: approved by the Foundation Board of the SCQM Foundation by written consent on May 21, 2014

On behalf of the SCQM Foundation Board

Dr A. Forster
President

Appendix I
to the rules of research and co-operation

Use of samples from the SCQM Biobank for study purposes

The rules of research and co-operation form the basis for study requests involving biological samples. The following points must additionally be observed:

Any rheumatologist actively involved[1] *in the collection of biological samples can submit study requests requiring biological samples.*

1. *The ethics approval for studies with biological samples must be obtained before the samples are supplied. A copy of the ethics approval is to be sent to the SCQM.*

2. *A study request involving biological samples must contain the following information:*
    a. *the number and type of biological samples required*
    b. *the amount (volume) of material required for the analysis*

3. *The applicant ensures that the samples are protected from unauthorised access and loss. This also applies to the data derived from the analysis of biological samples.*

4. *The following fees apply for the processing of biological samples (DNA extraction, aliquoting, storage, checkout, etc.):*
    - Serum aliquot: CHF 2.50 per aliquot
    - DNA aliquot: CHF 6.50 per aliquot
    The number of samples contributed by the applicant's institution is deducted when determining the cost of each study project.
    *Example: Institution X has contributed 500 samples to the Biobank. Dr Y from institution X makes a study request that requires 1,500 serum aliquots. The applicable fees for these aliquots are calculated as follows: (1,500-500)*2.50 = CHF 2,500.-.*

5. *The applicant covers the cost of transporting biological samples from the SCQM Biobank to the laboratory where the analyses will be performed.*

6. *The applicant covers the cost of analysing the biological samples.*

7. *The applicant ensures that the data derived from the biological samples are sent to SCQM in a suitable form (after consultation with the SCQM), where they are stored in the research database. The ownership of the data lies with the SCQM. The data can be used for future study projects, without consultation with the applicant. The costs of integrating the data into the SCQM database are covered by the SCQM.*

The Board of the SCQM Foundation approved Appendix I at its ordinary meeting on November 5, 2014.

Zurich, November 5, 2014

The President of the Foundation Board

Dr Adrian Forster