



## SCQM FOUNDATION

Swiss Clinical Quality Management  
in Rheumatic Diseases

### ***The SCQM data can be the basis for your next study.***

The officers of the SCQM Foundation welcome the chance for data collected across Switzerland over the years to be used for study purposes. We will gladly provide you with data for your next research project.

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<sup>1</sup> with the SCQM can submit study inquiries. The applicant must describe the purpose of the study and accept the provisions of this regulation.

### 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 in 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 these additional data lies in principle with the SCQM. The resultant costs must be borne by the applicant.

### 3. 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/> → Physicians → Research → Request form SCQM data.
2. The request is sent by the SCQM office to the head and members of the scientific committee of the relevant register for evaluation.  
The scientific advisory board of the Biobank is responsible for the evaluation of study requests with material from the SCQM Biobank.  
The request will be evaluated within 15 working days.
3. Comments from the persons mentioned under 2 above are combined by the scientific management of the SCQM and submitted together with the study inquiry to the foundation advisory board for evaluation.
4. The foundation shall finally decide by circular letter (e-mail) on the study requests. In the absence of a **dissenting vote** of a foundation advisory board the request will be approved after 15 working days.
  - i. In the event of one or more scientifically justified dissenting votes of the foundation advisory board the applicant shall be given an opportunity to address the issues raised.
  - ii. The foundation advisory board shall thereafter agree on the circular letter whether in the context of the suggested changes the request is to

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<sup>1</sup> 'Actively involved' means rheumatologists having registered data for at least 5 patients with the SCQM in the 2 years prior to the application.

be accepted. 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 advisory board, all documents are to be **treated confidentially** by all persons who have access to them in accordance with articles 3.2. and 3.4.
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 5.1 and 5.2.

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 data record for the certified study custom-made for the applicant.
  - ii. The SCQM reserves the right to send to the applicant in certain cases a raw data dump of the research database.

#### **4. Participation in studies**

The criteria governing who is entitled to authorship are listed under article 8.

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. Pin board for studies: The SCQM website provides a pin board for agreed 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 Advisory Board.

#### **5. Fees**

1. The expenditure on specific data inquiries or processing by SCQM is charged as follows: CHF 150.00/h for physicians and institutions, who have contributed patients in the database, as well as for main sponsors. CHF 250.00/h for all other clients.
2. Physicians and institutions, who have included patients in the SCQM database, are entitled to 10 hours support from a qualified SCQM specialist for data extraction and statistical evaluations per study project. Commencing with the 11<sup>th</sup> hour, additional charges for a study project will be levied in accordance with the charges set out in article 5.1.
3. Quotations will be provided on request.

#### **6. Changes to the study protocol**

1. In the event of a substantial change to the study request the applicant shall undertake to submit a supplement. This is submitted to the foundation advisory board and the head of the appropriate scientific committee. The decision-making process on the supplement submitted follows the process described in article 3.4, with a decision period of 5 working days.

#### **7. 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 which will check whether this corresponds with the underlying research request.

The work is passed on for information to the foundation advisory 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 advisory board and the head of the relevant scientific committee. The foundation advisory board shall thereafter decide by circular whether the suggested work may be submitted for publication. With a relative majority the work shall be accepted as valid.

The applicant undertakes, within six months after publication of a manuscript, to make available to the SCQM office about **5 sheets with the most important conclusions of the study and a copyright confirmation** (the SCQM will provide a template for the sheets). These sheets will be made available to the physicians cooperating with the SCQM on the log-in-protected SCQM online database and can be used for lectures (mandatory indication of source).

## 8. Authorship rule

(Reference: *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication* ([www.icmje.org](http://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 workProcurement 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](http://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](http://www.scqm.ch/sponsors)."*

**9. Publication of the studies on the SCQM website**

Studies and study projects are published as follows under the heading Research on the SCQM website:

1. **Pin board:** Granted study projects. Publication for 2 months. Prospective customers can register to participate.
2. **Current study projects:** This is where all projects not yet published are listed.
3. **Publications:** All study titles and authors are published. The Abstracts can be consulted via a link (pubmed).

**10. 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.

**11. 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.

Zurich, in November 2012

On behalf of the SCQM Foundation Board

Dr A. Forster  
President