SCQM
Swiss Clinical
Quality Management in
Rheumatic Diseases

SCQM Foundation
Aargauerstrasse 250
8048 Zürich

+41 43 268 55 77
scqm@hin.ch
www.scqm.ch

SCQM Rules of Research and Collaboration

The Swiss Clinical Quality Management in Rheumatic Diseases (SCQM) Foundation is a tax-exempted independent foundation (Art. 80ff of the Swiss Civil Code), that runs registries for patients with inflammatory rheumatic diseases, free of local, regional and personal interests.

With its online database, it offers participating patients and their treating medical professionals a multilayered record of the course and progression of inflammatory rheumatic diseases.

The collected coded clinical data and coded biological sample material of patients who provided informed consent can be made available by the SCQM for secondary research use.

This document formulates the rules for use of SCQM data for research purposes and as such forms an integral part of the contractual agreement on studies with SCQM research data.

Version: 2.0

Date: 20.11.2023

Next regular review date: 01.09.2026

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

Change history

Version Nr	Version date	Description, comments	Control
1.0	5.11.2014	Initial version	Foundation Board
2.0	20.11.2023	Total revision of all paragraphs	Foundation Board

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

Table of contents

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

1. Defined Terms

Data: Data shall in this document mean both (pseud-)anonymized clinical data, biomaterial and or imaging data of patients followed-up in the SCQM who have provided informed consent for research use of their data. Specifications on rules and regulations around different types of data are detailed in the data and material transfer agreement.

Study: Research project for which data is requested

Study protocol: Protocol as submitted and authorized by the responsible authorities

Study request Form: SCQM template for submission of a data request for a study.

Study sponsor: Person or institution based or represented in Switzerland who assumes responsibility for initiation, management and funding of the study in Switzerland.

Principal investigator (PI): Main requestor of data and project leader of the study. Throughout this document, it is assumed that the PI takes the role of the study sponsor. Roles must be declared in the study request form.

Active contribution: Active contribution to the SCQM is evaluated for the clinical department of the PI and is defined as a minimum of 100 SCQM visits per calendar year, of which at least 10 must be inclusion visits.

Active contributor: A clinical unit that fulfils the rules for active contribution.

SCQM research partner: active contributor with academic / research activities involving SCQM cohorts. SCQM research partners are listed on the SCQM website.

SCQM research committee: Committee responsible for reviewing and approval of the study requests.

SCQM Rules of Research and Collaboration (RRC): Refers to this document.

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

2. Application procedure

2.1. Who can apply

Access to SCQM Data shall only be granted to a Principal Investigator (PI) who possesses the necessary research qualifications and demonstrates the capacity, including adequate infrastructure, to conduct the study in accordance with ethical guidelines and legal requirements.

Within the scope of these Rules of Research and Collaboration (RRC) and throughout the study, the PI must take on the obligations of the study sponsor. The PIs shall be solely accountable for the study's initiation, management, and financing. Furthermore, the PIs shall ensure that all aspects of the study are conducted diligently, adhering to the highest professional standards, and in full compliance with applicable legal statutes, regulations, and industry standards.

The PI agrees to defend, indemnify and hold SCQM its director and its employees harmless to the fullest extent permitted by applicable laws, from and against any and all claims and any related loss, damages, costs and expenses, which SCQM, its director and/or its employees may incur or suffer, or with which any of them may be faced, arising out of a breach by PI of any legal obligations or any terms of the RRC.

2.2. General procedure

Before submission, the PI is invited to contact the SCQM office and request consultation on the study idea in terms of e.g. feasibility and/or design questions.

Upon submission for initial review, the SCQM scientific staff checks for potential conflicts of the study with any ongoing studies. Such potential conflicts must be resolved amongst the respective principle investigators before further processing of the request.

The SCQM research committee performs an initial review of the submitted SCQM study request form. This review will allow the PI to get scientific input on the study idea.

Upon initial review by the SCQM research committee, approval by the responsible authorities (see “legal and regulatory requirements” below) is required. Finally, full review by SCQM research committee is performed for final approval. Details on the approval procedures can be found on the SCQM website.

The information in the study request form is handled confidentially by all persons who have access to it.

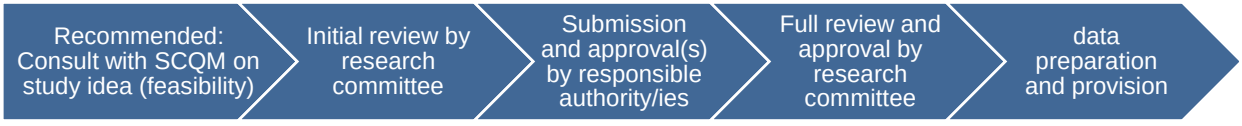

Figure 1: General procedure for SCQM data requests

2.3. Additional procedures for studies with commercial interests

When the study pursues commercial interests (e.g. aim to patent or licence a product based on the research results or to give insights into existing products), these must be declared and additional legal and procedural rules may apply.

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

2.4. Legal and regulatory requirements

In order to initiate the study, all legal and regulatory requirements must be met. Compliance with these legal and regulatory requirements is essential to maintain the integrity of the study and protect the rights and interests of research participants, institutions, and researchers. The PI is advised to consult with legal experts, institutional review boards, and relevant regulatory authorities to ensure full adherence to all applicable laws and regulations. Legal requirements depend on the type of the study. The PI is responsible for classifying the study and clarifying and abiding to any legal and regulatory requirements for the study.

Authorization of the study or respective waivers by the responsible approval authorities1 must be made available to the SCQM before data provision. This also holds for any amendments of the study protocol.

2.5. Extending SCQM data collection for a study

The PI must detail any additional questions and/or data collection requests in the SCQM study request form. Data ownership of any data captured in the SCQM online database will per default lie with SCQM.

Offers for implementation will be provided by the SCQM and the PI must bear the full costs of the implementation.

2.6. Study budget and financing

The PI is responsible for supplying funds to cover the study budget. SCQM does not provide research funds for studies.

Any work done by SCQM for the study (see below) must be covered by the study budget. As a minimum, such work includes the SCQM internal administrative work related to procedures described in these regulations and work related to data provision. SCQM provides budget estimates for such work upon request.

2.7. SCQM research support facilities

The SCQM offers research support services to researchers such as: consultation on the study design, feasibility analyses, writing of a statistical analysis plan, data cleaning work, data analysis, graphical representation of results and contribution to manuscript preparation. For prospective studies, the SCQM may also provide work in the planning, implementation and management/coordination of studies. Details and conditions are available on the SCQM website or on request.

3. Data provision

Following acceptance of the study request, receipt of necessary approval document(s) by responsible approval authorities and fully signed contractual agreements, the SCQM office shall make the required data available to the PI.

The PI is responsible for the secure transfer, storage, handling and sharing of the data throughout the duration of the study as well as during the data retention period after publication of the study.

[1] https://kofam.ch/de/forschung-am-menschen/akteure-und-ihre-rechte-und-pflichten

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

3.1. Rules and conditions for data provision

The rules and conditions for data provision depend on whether the PI's professional affiliation is with an active contributor. All costs for data extraction, preparation and provision arising at the SCQM for the study must be covered by the PI (offers will be provided by SCQM upon request).

Additionally, for non-contributing PIs:

- data sharing fees apply (tariffs available upon request),

for PIs from active contributors:

- data sharing fees are waved.

4. Study progress reporting

The PI will be requested to submit a brief study progress update at least once annually for the duration of the study.

5. Authorship rules

5.1. General authorship rules

The SCQM guidelines are based on the guidelines of the International Committee of Medical Journal Editors (ICMJE) ("Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication"), last updated in December 2017, and published online www.ic-mje.org).

Authorship credit should be based on

- Substantial contributions to the conception or design of the congress abstract or manuscript ("work"); or the acquisition, analysis, or interpretation of data for the work; and
- Drafting the work or revising it critically for important intellectual content; and
- Final approval of the version to be published; and
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take responsibility for appropriate portions of the content.

Persons who meet more than one but fewer than all 4 of the above criteria for authorship should not be listed as authors, but should be acknowledged. Examples of activities that alone (without other contributions) do not qualify for authorship are acquisition of funding; general supervision of a research group or general administrative support; writing assistance, technical editing, language editing, and proofreading.

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

5.2. Specific authorship rules for studies with SCQM data as main data source

Engaging key stakeholders in the area of inflammatory rheumatic diseases in the study will contribute to the quality of the study by contributing to a) addressing clinically relevant questions, b) providing thorough understanding of the source of the data, c) increasing the uptake of the research findings and d) laying a basis for potential implementation work based on the research findings.

The below rules apply for studies with data from SCQM as a main data source:

The PI is first or last author on manuscripts based on the study

- The Co-investigators are intended to co-author manuscripts based on the study.
- The PI welcomes collaboration of persons with expertise in the subject area of the study and must duly consider any collaboration requests.
    - The SCQM runs a “study pinboard” on its website to inform the research community about new studies and allow interested persons to approach the PI.
- Minimal requirements to constitution of co-investigators in the study team: The PI must invite
    - all SCQM research partners to nominate at least one co-investigator,
    - at least one practice-based rheumatologist, who is actively contributing data to the SCQM and
    - at least one patient partner[2].
- Responsibilities of the PI for collaboration with the study team: The PI must
    - invite co-investigators before submission of a study request to the SCQM and
    - proactively request and encourage the involvement of the co-investigators.
- Responsibilities of the co-investigators for collaboration in the study team: The co-investigators must
    - actively opt in to collaboration request,
    - actively engage in the study and respond to PI requests and
    - fulfil authorship rules listed below (section 12)
- When co-investigators do not respond to requests from the PI and respective reminders, the PI can exclude co-investigator from the study team. In such a case, the PI will inform the respective co-investigator accordingly and will document attempts to involve him or her. These documents will be shared with SCQM upon request.

The research committee may approve exceptions to the above rules on the study team composition and authorship (e.g. in studies using data from only one institution, in pilot studies or methodological studies).

5.3. Specific authorship rules for studies with SCQM and other data sources

In studies with SCQM data and data from other sources (e.g. international collaboration studies or studies in collaboration with other registries) at least one SCQM research partner must be part of the study team. One of the SCQM research partner(s) must act as the SCQM representing co-investigator and takes over the responsible for abiding to the SCQM RRC in context of the study. The number of SCQM research partners involved should depend on the relative contribution of SCQM data to the study and is to be negotiated between the SCQM representing co-investigator and the PI of the study.

[2] https://www.scto.ch/en/patient-and-public-involvement/ppi-resources.html

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

6. Abstracts & publications

The SCQM recommends researchers to use guidelines and checklists for analysing and reporting in observational data studies. Examples are resources from STRATOS, STROBE (EQUATOR) and EULAR[3] on analysis of and reporting on observational data.

The following points are valid for both projects with SCQM data as main data source and projects with multiple data sources, unless stated otherwise.

6.1. Pre-submission manuscript checking by SCQM

Before submission of results on the study in the form of abstracts, preprints or manuscripts for publication, these must be checked by the scientific staff of the SCQM office to ensure that SCQM is referenced appropriately.

The periods for the submission for manuscript checking are:

- Abstracts for congresses: at least 5 working days before submission
- Preprints or manuscripts: at least 10 working days before submission

6.2. Data availability statement

The coded individual patient level data analysed during the study may not be published on pre-print or journal servers without explicit consent by the SCQM. Clearance for data publication and a data availability statement is provided by the SCQM upon request.

6.3. Lay summaries

Upon publication of a manuscript, the PI must provide a lay summary (plain language summary) that SCQM is free to use for its communication purposes. Recommendations on lay summaries are available from EULAR[4].

6.4. Reference to SCQM in studies with SCQM as main data source

In studies where SCQM is the main data source, SCQM must be referenced appropriately, e.g. in the abstract text, methods section and acknowledgement section.

Wording of acknowledgement & conflicts of interest:

- **SCQM data-contributing institutions** should be acknowledged as follows: "… A list of participating practices and hospitals contributing to the SCQM registries can be found on the SCQM website (https://www.scqm.ch/en/about-scqm/active-institutions/).
- **SCQM financial support** should be declared as follows: "The SCQM Foundation is supported by [LIST COMPANIES AND OTHER SUPPORTING PARTNERS as listed on SCQM website (https://www.scqm.ch/en/partners/)]. SCQM supporting partners had no role in the study design or in the analysis and interpretation of the data, the writing of the manuscript or the decision to submit the manuscript for publication."

[3] STRATOS: http://www.stratos-initiative.org/, EQUATOR: https://www.equator-network.org/ EULAR provides "points to consider" publications in these areas. Specific recommendations on guidelines / checklists will be provided upon request.

[4] https://www.eular.org/lay_recommendations.cfm

SCQM
Swiss Clinical Quality Management in Rheumatic Diseases

- **Study funding:** Companies or other funding agencies that funded the study and/or collaborated in the study must be referred to transparently and separately from the reference to SCQM.

In oral presentations and posters, the logo of the SCQM must be included. A high-resolution image of the logo is provided by SCQM.

6.5. Reference to SCQM in studies with SCQM and other data sources

The form of referencing of the SCQM shall depend on the proportion of data contribution from the SCQM in the study. In epidemiological or clinical multi-cohort collaborations including SCQM data, the name "Swiss Clinical Quality Management in Rheumatic Diseases" must be mentioned either in the author list or other appropriate sections of the main manuscript. If the SCQM contributes more than 10% of the data or more than 100 patients, the SCQM acknowledgement to contributing institutions, as described above, must be added to the main manuscript.

7. Termination of the study

If the study is terminated prematurely, the PI must inform the SCQM immediately.

If the study duration, as indicated in the contractual agreement with SCQM around the study, is expected to be exceeded, the SCQM office will invite the PI to submit an application to prolong the study duration. Prolongation applications must include justification for delay and updated timelines and are handled formally as study amendments. In the absence of a request for prolongation at the contractually set expiration date, the study will be closed and a new study request will be needed to re-initiate or continue the study.

8. Data privacy

The SCQM will use the name and institution name of the PI and of the members of the research team to inform its stakeholders about ongoing studies and new publications via its communication portals (e.g. website study pinboard, website news, news email, social media).

The PI and anyone working for this study must follow the rules on data protection, e.g. the Swiss data Protection Act, at their own cost. Negligence or other errors resulting from the PI or their team's action, which causes costs or losses for SCQM, must be indemnified by the PI.

The study Contractual agreements between SCQM and the PI define further conditions to ensure data safety and security.

Approved by the Foundation Board of the SCQM Foundation on 20.11.2023

Foundation Board president:

Dr. M. Andor

28.11.2023

DocuSigned by:
21A12815CDA643F...

Foundation Board vice-president

Prof. Dr. Diego Kyburz

07.12.2023

DocuSigned by:
Diego Kyburz
6CA1093490C1463...