Request form for the use of SCQM data:

*Please mail to the form to research@scqm.ch*

*Data use for research underlies the SCQM Rules of Research. Please visit our website and carefully read these.*

*Fees may apply for provision of data. Cost estimates will be provided upon request.*

*The italic text contains supporting information on what is expected in the different fields of the form and should be replaced by details on the project.*

*The SCQM offers consulting on study feasibility given the collected data, e.g. on design, sample size / power calculation. Data preparation and analysis services can also be provided. Please contact us for more information.*

|  |  |
| --- | --- |
| 1. Title of study
 |  |
| 1. Name, position and working address of principle investigator / sponsor of study
 |  |
| 1. Involvement of principle investigator in SCQM data-entry
 | *According to the Rules for Research and Collaboration (RRC), data-sharing fees are waived for principle investigators from contributing clinical units (for more details, we refer to the RRC).**Please describe crudely the involvement of you or your clinical division/institution in terms of duration of collaboration with SCQM and estimate of yearly contribution in terms of inclusions and follow-up visits.**For principle investigators from institutions that do not contribute data to SCQM, this field is not applicable.* |

|  |  |
| --- | --- |
| 1. Name, position and addresses of sub-investigators and collaborators from SCQM Research Partners
 | *For research with Swiss data only, all major data contributing Swiss research institutions must be invited to collaborate (and co-author) in the research project.* *A list of Research Partners is provided upon request.**For international collaboration studies, please list the Swiss collaborators on this project and their role in the project.* |
| 1. Name, position and addresses of patient partners in this study
 | *The SCQM expects the involvement of patients in research projects with its data. At least one (ideally two or more) patients should be part of the investigator team.* *The principle investigator must invite at least one patient to act as co-investigator (see RRC for more details). Please provide details of the patient partners here or describe your efforts in setting up collaboration with patient partners.* |
| 1. Name, position and addresses of office rheumatology partner
 | *As specified in the SCQM RRC, at least one office rheumatologist must be invited to collaborate in the investigator team for the study (see RRC for more details). Please provide details of this co-investigator here or describe your efforts in setting up collaboration with such co-investigator(s).* |
|  |
| 1. **Project description**
 |
| 7.1. Lay summary incl. description of clinical relevance | *Please provide a lay summary of the project and its underlying research question with a focus on clinical relevance for patients and physicians, if applicable.* |
| 7.2. Background | *Please provide some background information including prior work on the subject.* |
| * 1. Research question
 | *Please describe the (clinically relevant) research question of interest.* |
| 7.4 Study design | *In most cases, studies with SCQM data are retrospective analyses of the prospectively collected registry data. In some cases, prospective studies are implemented and ran via SCQM. Please specify accordingly.**If a comparative study is intended, we advise the principle investigators to follow the approach of “emulating clinical trials in observational data studies” (see e.g. doi*[*10.1093/aje/kwv254*](https://doi.org/10.1093/aje/kwv254)*).*  |
| 7.5. Study population / in and exclusion criteria | *Which diagnosis/diagnoses? Clinical diagnosis by the rheumatologist sufficient for inclusion or classification criteria to be met?**Are there exclusion criteria in terms of e.g. age, prior exposure to treatments, prior comorbidities?* |
| 7.6 Study period | *Please provide the start and end date of the time period during which SCQM’s prospectively collected data will be considered. This may e.g. be a time when certain drugs of interest were available.* |
| 7.7 Follow-up period | *Please provide the start and end of follow-up of the patients within the study.* *For example:*  *- A patient’s follow-up in the study starts at the maximum of beginning of study period and date where the inclusion criteria are first met.* *- A patient’s follow-up in the study ends at the minimum of the occurrence of the outcome of interest and the last recorded visit in the SCQM.* |
| 7.8 Exposure(s) of interest | *if applicable**E.g. treatments or life-style factors that will be compared in the study*  |
| 7.9 Outcome measures | *Please describe with which outcomes the objectives will be investigated.* |
| 7.10 Statistical methods |  |
| 7.11 Sample size / power considerations | *Please consider what (clinically relevant) difference in outcome is of interest for the comparison (exposure(s)) of interest and derive the respective required samples size to answer the question of primary interest with an adequate power?* |
| 8. Imaging | ***Fees are charged for provision of images (X-rays). Tariffs available upon request****Number of patients for whom images are requested:**Number of time-points per patient: (cross-sectional, i.e. only 1 or 2 time-points per patient or as many time-points per patient as possible).* |
| 9. Biobanking | ***Fees are charged for provision of biosamples. Tariffs available upon request****Quantity of serum required**DNA required yes / no* |
| 10. Database development | ***Database development costs must be covered by the requestor. Offers will be provided upon request.****Are any new questions or new questionnaires necessary for this study? Please deliver as much detail as possible.* *Is it a validated questionnaire? What languages (DE, FR, IT) are available?* *Should the questions be asked once, multiple times, or forever? When should the questions be asked (at inclusion, yearly control, intermediate control, or, if patient reported, independent of doctors consultations)?* |
| 11. References |  |
| 12. Time-lines | *Please provide timelines here.* |
| 13. Ethical approval | *State whether and from which ethics committee an ethical approval has been obtained or will be obtained.* *Some ethics committees wave ethical approvals for studies using already collected data, that can be deemed anonymous for the researcher. Please consult your responsible ethics committee and describe the situation for your study here.* *An ethics confirmation or written waiver from the ethics committee is required before data provision by SCQM.* |
| 14. Other legal aspects (insurances etc.) | *Who is the project sponsor? (if different from principle investigator).* |
| 15. International collaboration / data sharing | *Is data sharing abroad intended?**If so, please attach statement / contract describing international collaboration incl. handling of shared data* |
| 16. Budget aspects concerning SCQM  | *E.g.**- Costs for consulting services by SCQM around feasibility (study design and sample size / power calculations)**- Costs for images and/or biosamples (see pt. 6 and 7)**- Costs for further development of the data collection (see pt. 8)**- Costs for preparation, delivery and/or analysis of data by SCQM*  |
| 17. Funding sources | *Please list the sources of funding that you have or expect to find to cover the project costs* |
| 18. CV of principle investigator |  |
| **The following fields will be completed by SCQM and/or the reviewing body** |
| Review comments |  |
| Data clearance approved by board of SCQM foundation  | Date: |
| SCQM clearance congress abstracts / manuscript | *The SCQM checks whether publications are in line with request and whether the SCQM is references / acknowledged appropriately*Name of SCQM staff:Date: |

I hereby confirm that I wish to request access to SCQM data for the above-described research. I understand that my personal data will be used for administrative purposes by SCQM and will, for this purpose, be disclosed to members of SCQM entities.

Place, date:

Name, signature: