Guideline for handling the data of the Multiple Sclerosis Register of the DMSG, Bundesverband e.V. (Use and Access Policy)[1]

The basic idea of this guideline is a transparent and trusting cooperation of all parties involved in the use and publication of the register's data.

MS Research and Project Development GmbH

In 2001, the Bundesverband der Deutschen Multiple Sklerose Gesellschaft e.V. (Federal Association of the German Multiple Sclerosis Society) initiated a new project, the establishment of a Multiple Sclerosis Registry (MS Registry) for Germany. The MS Forschungs- und Projektentwicklungs-gGmbH (MSFP), a subsidiary of the DMS Foundation established by DMSG, was commissioned to operate the MS Register.

Aims of the MS Registry

Based on over 15 years of experience, the aim of the MS Registry is to establish a permanent data repository for health care research in the field of multiple sclerosis, which guarantees data collection, storage and provision over decades. A participatory data collection system that involves both doctors and patients in the data collection process is to be implemented. The Registry will increasingly enable monitoring of the care of MS patients, support scientific research projects and aim to exchange data with other national and international repositories.

The questions that can be dealt with by the register include but are not limited to the following topics:

- Statements about the age structure of the documented patient population and the usual age at the onset of the disease as well as the time to diagnosis,
- Statements about the course of the disease and the severity of the disabilities caused,
- Statements about the type of care used,
- Statements about the use of treatments and therapies,

[1] For any dispute around these rules, the latest version (tob e found on the website of the MS-Register) of this document in the original German Version shall be binding.

- Statements about restrictions in employment of MS patients,
- Statements about the side effects that occurred during treatment

At the international level, the MS Registry cooperates e.g. in projects of the European Multiple Sclerosis Platform (EMSP) and the MS International Federation (MSIF) and participates both in the definition of a European minimum data set and in the conduct of studies and initiatives to harmonise European registry data and structures.

Scientific Monitoring Group of the MS Registry

Composition

The names and institutions can be found on the MSFP website. The Scientific Advisory Group is composed of members from the fields of epidemiology, medical informatics, medical statistics and neurology.

Tasks of the Scientific Advisory Group of the MS Registry

In addition to the basic function of this body to discuss current developments in the Register and to coordinate future changes to the Register, the Monitoring Group performs among others the following project-related tasks:

- Approval or rejection or invitation to revise analysis projects on the basis of the project outlines
- Assignment of analysis projects
- Monitoring the execution of analysis projects; if there is no activity, the project award can be withdrawn.
- Comments before submitting abstracts for congresses or articles to journals (national or international)
- Advice on data analysis and preparation of or cooperation in congress contributions and scientific publications in journals

Access to the data

(1) The MSFP provides a current data record description (in addition to the print templates of the data record) of the MS registry on request.

(2) In principle, those institutions or researchers who have contributed to the MS registry have access to the MS registry data.

(3) The MSFP advises interested scientists, institutions and companies on the application of analysis projects.

(4) External applicants may carry out analysis on the register data only in cooperation with the MSFP or members of the Scientific Advisory Group on aggregated data. For reasons of data protection and transparency, the original data remain in the research database of the MS registry, to which only MSFP staff have access.

(5) Scientific questions can be dealt with by members of the MSRG on the basis of the overall data - after a project plan has been drawn up beforehand and after a positive statement by the scientific support group and positive approval by the management.

(6) The data used by the aforementioned group of persons for evaluation purposes is available exclusively in pseudonymized form.

(7) As a rule, evaluations are carried out on anonymous data, as long as the purpose of the evaluation does not require a personal feedback of the results to the patients. The decisive factor here is always the extent of the patient's consent to contact. If a person-related feedback makes sense, pseudonyms specific to the analysis are used, which can be dissolved via the MSFP to the register pseudonyms and centers.

(8) Documenting centers can always access their MS registry data via standardized, pseudonymized exports provided by MSFP.

(9) A special case with regard to the inclusion of the MSRG, as well as the time schedule can be requirements of (supervisory) authorities (EMA/BfArM/PEI/G-BA), if this is required due to the urgency of the request. In this case, the MSRG shall be informed of the request as soon as possible.

Procedure for a Register-Related Analysis Project

(1) A group of authors develops a project idea and submits an application with concrete questions to the MS registry (see Appendix A).

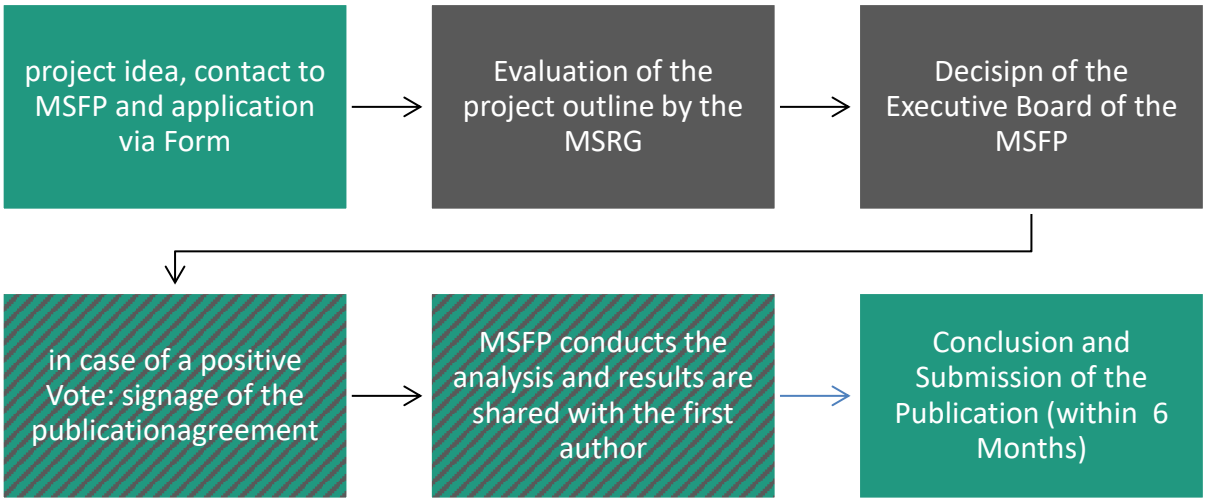
(2) After a positive statement by the scientific support group and a positive decision by the management of the MS Registry, a publication agreement (see Appendix B) is signed by the first author, the responsible biometrician/statistician and the MSFP. The first author and the MSFP each receive a copy.

(3) The majority of the Scientific Advisory Group must vote in favor.

(4) The results of the analysis are made available digitally to the first author.

(5) A publication should be completed and submitted within 6 months of the results being made available.

(6) Deviations from this procedure must be clarified in advance with the scientific support group and the MSFP.



- Author(group)
- MSFP / scientific advisory group of the MS Register (MSRG)

Application for a register-related evaluation project

Each application (see Annex A) is based on a written project outline with the following contents:

- (Work) title of the project
- Background (why this analysis should take place, which previous knowledge/data and possibly own preparatory work exist)
- Question formulated as scientific hypothesis (for inductive/explorative statistical methods)
- Method (statistics, study design)
- Information on the persons involved
- Information on the time framework conditions
- Information about the planned publication of the data (which journal, which congresses, etc.)
- Authorship with order

(1) In principle, the outline should be formulated in such a way that it becomes clear whether the conditions for acceptance as a scientific publication can be fulfilled. The sketch can be submitted to the MSFP at any time by e-mail (kontakt@msregister.de).

(2) If external persons or institutions or companies apply for evaluation projects, the responsibility for these projects lies with the applicants.

(3) Adequate financing of the expenditure, in particular for analysis projects of external persons, is determined individually before the start of the project.

(4) The scientific support group of the MS Registry will meet as needed, possibly in the form of a telephone or web conference, to reduce costs, time and bureaucracy.

(5) The scientific support group of the MS registry can vote in a round robin procedure if necessary.

Evaluation of the project outline

(1) The Scientific Advisory Group discusses:

   a. whether the planned question is appropriate,

   b. whether thematic overlaps exist and

   c. whether the choice of co-authors is appropriate,

   d. and informs the applicant of its decision.

   Only then can the analysis of this question begin.

(2) Other working groups also interested in the topic have the opportunity to express their interest to the scientific support group, which establishes contact with the first authors. In the event of conflicts between the interested parties, the date of receipt of the first qualified project outline shall be decisive.

(3) After the discussion and the positive vote of the scientific support group and the MSFP management, the topic will be handed over to the applicants.

(4) The main applicant is now the person responsible for the project and the first author. Co-authors are to be named on the publication as presented in the application. Other authors should, as prescribed by Good Scientific Practice, only be named if they have made a significant contribution. The scientific advisory group of the MS registry should be mentioned in an appropriate place, a naming of individual members is only foreseen with their participation. Where possible, publications should be accompanied by an annex listing all participating centers whose data have been incorporated into the project.

(5) The manuscript is sent by the MSFP to the members of the scientific advisory group for comment before submission. The feedback period is generally 30 days, in justified cases even less, with a minimum of 7 days. If the first author does not receive any feedback from one or more members of the scientific support group within the communicated deadline, the manuscript is deemed to have been approved.

(6) If possible, the analysis team should present the results at the next meeting of the Scientific Advisory Group, but at least the final publication should be made available to the MSFP and the Scientific Advisory Group.

co-authorship

(1) The author(s) present the results at congresses and/or publish them in scientific articles. The author who produces the publication is listed as the first author, all those actively involved in the development of the analysis project, in the analysis of the data and in the

publication are to be named in alphabetical order as co-authors. The scientific advisory group of the MS registry is referred to in the appropriate place.

(2) As a rule, only one person per center should be co-authored on each MS Registry publication in order to do justice to the multi-center nature of the MS Registry. Exceptions must be requested in advance from the Scientific Advisory Group, explaining the specific contribution of each co-author.

(3) Due to the special effort involved in manuscript preparation, coordination and biometrics/statistics, two authors may also be adequate here.

(4) Co-authorship of clinic or department heads who were not actively involved in the development of the problem, the data analysis and the writing of the publication is not desired.

(5) In the case of international cooperation projects, cooperation with basic researchers or groups that contribute special knowledge (epidemiology, genetics, etc.), a fair regulation is agreed in advance.

(6) Changes to co-authorships without consulting the scientific advisory group are not permitted.