Application for data output from the ReMuS registry

This form shall be filled-in by researcher in charge to gain aggregated level data output from the ReMuS registry.

In case of any questions or support request, please contact ReMuS registry via email: data@multiplesclerosis.cz.

Registry ReMuS refers to registry of the patients with diagnosis of multiple sclerosis in The Czech Republic and is maintained and operated by the Manager.

Administrator of the ReMuS registry is IMPULS Endowment Fund.

Authorized Person refers to a subject (natural person or legal entity) entitled to receive data output from the ReMuS registry.

Anonymized data is selected patient data which cannot be related to any particular patient.

Patient stands for individual person, who granted its consent to process one's personal data in the ReMuS registry.

The "**Application for data output from the ReMuS registry**" will be treated according to the documents: "**Data release information**" and "**Memorandum of cooperation**" (to be downloaded at www.multiplesclerosis.cz).

Please return filled in form to data@multiplesclerosis.cz. The applicant's eligibility and the feasibility of the analysis are subject to independent examination by **The Clinical Neuroimmunology and Liquorology Section** of The Czech Neurological Society of The Jan Evangelista Purkyne Czech Medical Society and **The Managing Board of the IMPULS Endowment Fund**. In order to allow the analysis to be carried out, the consent of both parties above has to be granted. Subsequently, a "Data Processing Agreement" is concluded between the **Authorized Person** and the **Administrator**.

ReMuS®
MULTIPLE SCLEROSIS
PATIENT REGISTRY

Application for data output from the ReMuS registry

PROJECT NO.:[1]

1. Authorized Person (applicant)

Title(s):	
First name:	
Surname:	
Institution/company:	

Please include name, address, and country.

Phone:	
E-mail:	
Project relevant position title:	

2. Other team members / collaborators participating on the project below (first name, surname, title, job title, institution / company, phone, e-mail, country)

First name, Surname, Titles	Job title / Institution or company	
Phone	E-mail	Country
First name, Surname, Titles	Job title / Institution or company	
Phone	E-mail	Country

In case more relevant team members shall be stated, please attach separate list containing information above.

3. Name of the project

[1] FOR INTERNAL USE ONLY

4. Project annotation

5. Project objectives – primary and secondary outcomes

6. Tested hypothesis

7. Project framework specification

a. Project type

ACADEMIC ☑ COMMERCIAL ☐

b. Financial support (funding by pharmaceutical company, granting agency, etc.):

YES ☐ NO ☑

c. Funding source/s (subject name, project identification, contact details):

d. Planned publication aim (e.g. journal, conference presentation, etc.):

8. Technical requirement specification

8.a. Inclusion / exclusion criteria:

a. **Period** / duration of follow-up:

Last available registry data: ☑ YES ☐ NO

If not, please specify years:

b. **Demographic criteria** (e.g.: restrictions by age, sex, death details, etc.):

c. **Diagnosis criteria** (e.g.: restrictions by date of onset, diagnosis of MS / confirmation, MS classification, secondary progression from date, etc.):

d. **Visits related criteria** (e.g.: restrictions by EDSS, employment status, and social reimbursement status, etc.):

e. **Relapses related criteria** (e.g.: restrictions by date of relapse, duration of relapse, relapse severity, relapse related treatment, etc.):

f. **Concomitant diseases criteria** (e.g.: restricted by occurrence of malignancy, non-melanoma skin cancer (NMSC), Herpes zooster, PML, etc.):

g. **Paraclinical evaluation criteria** (e.g.: restricted by availability or results of MRI, Liquid Cerebrospinal Fluid (LCS), evoked potential, laboratory exam, AqP4, etc.):

h. **Treatment criteria** (e.g.: restricted by MS specific treatment, symptomatic treatment, non-pharmacological treatment, or specific drug treatment, etc.):

i. **Pregnancy criteria** (e.g.: restricted by date of pregnancy start, date of child's birth, number of children, reported abnormalities, breastfeeding status or length, termination/abortion, etc.):

j. **Adverse events criteria** (e.g.: restricted by date of AE, severity, type, etc.):

8.b. Requested analysis variables (data output content):

a. **Demographic data**:

b. **Diagnosis**:

c. **Visits**:

d. **Relapses**:

e. **Concomitant diseases**:

f. **Paraclinical evaluation**:

g. **Treatment**:

h. **Pregnancy**:

i. **Adverse events**:

9. Please specify requested statistical analysis (analysis type and its content):

10. Budget

Provide expected budget costs for project participance of the ReMuS registry.

11. Attachments

a. mandatory:

- project / study protocol, if available
- data output structure, if available
- resumé of the project leader (applicant) and team members[2]

b. optional (if applicable, please specify):

12. Other

Please provide any important information not mentioned above.

13. Signature of the applicant

Signed in _____ on _ _ . _ _ . _ _ _ _

_____

Signature of the Authorized Person *(applicant)*

_____

[2] Applicable for academic project.