

Information Document on the Processing of the Personal Data of Patients in Connection with the Register of Patients with Multiple Sclerosis (ReMuS) in the Czech Republic

Dear Madame, dear Sir,

we would like to inform you that **IMPULS, Foundation Fund**, organisation ID no. 261 69 428, having its registered office in Prague 2, Kateřinská 30, postcode 128 08, registered in the Register of Foundations maintained by the Municipal Court in Prague, Section N, File 325 (hereinafter referred to as the “**IMPULS**”), collects, processes and maintains certain personal data (including sensitive data) of patients with multiples sclerosis in a register in the Czech Republic (hereinafter referred to as the “**ReMuS**”) in accordance with Act No. 101/2000 Sb. (*Sb. = Collection of Laws*), on Personal Data Protection and Amendments to Certain Acts, as amended.

We kindly ask you to read carefully the presented information concerning the ReMuS and the processing of personal data within this register. Before signing the consent with the processing of your personal data in the ReMuS, you can discuss the information stated below as well as the ethical issues related to the register not only with your attending physician or the person stated as the contact in this document but also with your friends or family members.

1. Why the ReMuS Was Created

In a number of European countries, there have been registers of patients with multiple sclerosis (hereinafter referred to as “**MS**”) kept for decades. Data in these registers are collected in order to obtain information on the prevalence, incidence and course of MS, its clinical symptoms, incidence of MS attacks, treatment of MS, disability, associated diseases and causes of death. Today, the registers in which these data had been collected abroad before the era of effective biological treatment, provide valuable information on the extent to which this treatment is able to postpone disability, whether its timely commencement is crucial and whether it extends the period of ability to work. It is exactly the comparison between the data from a period in which there was no effective treatment and the data from present time, which shows how the quality of life changes thanks to effective treatment.

Since MS is highly variable, it is also possible to use these data to search for factors, which pose a risk for incidence of MS itself as well as for ineffectiveness of the treatment and faster progression of MS. The information on the course of MS also allow the payers of medical care to better plan their finances, which are necessary for treatment of this disease. The information on effectiveness of treatment also help to better choose treatment and possibly change treatment as necessary.

In the Czech Republic, before the ReMuS was created, these data were only contained in the medical files of individual patients in individual medical facilities providing MS treatment (hereinafter “**MS Treatment Centres**”). There was no possibility to process these data digitally and use them for scientific purposes to show whether and how the practice and the results of MS treatment in the Czech Republic are different from the practice and results abroad. Also, there were no data collected on a long-term basis, which could be periodically processed to provide both the professional community and the general public with a notion of the severity and course of MS and the effectiveness of its treatment.

This is why the ReMuS was created in the Czech Republic. This was done thanks to the joint efforts of the professional community (the Section for Neuroimmunology and Liquorology of the Czech Medical Association of J. E. Purkyně (ČLS JEP)) and the IMPULS Foundation Fund, which took on the task of organising and managing this register, including raising funds for its administration.

Both the personal data of patients with MS who were or are treated in MS Treatment Centres (whether using conventional treatment methods or using what is referred to as “biological treatment”) and the personal data of those patients, in whom MS diagnosis is being considered are processed in the ReMuS in order to make it possible to provide credible statistics on MS epidemiology and possibly on its growing incidence based on the outputs from this register.

2. Processing of Your Personal Data in the ReMuS

The processing of your personal data by the IMPULS Foundation Fund in the ReMuS will take place in accordance with the applicable provisions of the Personal Data Protection act in such a way so that your personal data and privacy are protected.

The actual collection of personal data in the ReMuS will take place as part of your regular visits to MS Treatment Centres and will not cost you any extra time spent in the physician's office or any financial expenses and no special activities will be required of you.

2.1. Purpose of Collecting, Processing and Maintaining Personal Data

In the ReMuS, your personal data will be collected, processed and maintained for the following purposes:

- monitoring the incidence of MS;
- assessing the epidemiological situation, i.e. the information the prevalence, incidence and course of MS, its clinical symptoms, incidence of MS attacks (including information on the efficacy of medicinal products), disability, associated diseases and causes of death;
- providing outputs for monitoring the costs and effectiveness of medical care and medicinal products;
- evaluating the information for payers of medical care, other public institutions and manufacturers of medicinal products;
- evaluating the severity of MS and its social-economic impacts; and
- scientific and statistical purposes.

2.2. Scope of Collected, Processed and Maintained Personal Data

The IMPULS Foundation Fund collects, processes and maintains your personal data in the ReMuS only in the scope necessary for accomplishing the afore mentioned purposes of the processing of personal data. In order to prevent loss of the link between the personal data in the ReMuS and the patient and the consequent loss of the scientific informational value of the ReMuS, it is necessary to process your basic identification and contact data and certain other data in the ReMuS in addition to your personal data relating to the MS (including sensitive personal data) in order to maintain traceability of individual patients (for example, when they relocate).

The scope of personal data collected, processed and maintained in the ReMuS is described in Annex 1 to this document.

The scope of these data is not much different from the data that have been recorded in your medical file up until now. This means that it is only a partial systematic digitisation of that which has already been included in your medical file.

2.3. Who and in What Way Processes Personal Data

Your personal data will be collected, processed and maintained in the ReMuS by the IMPULS Foundation Fund through its own employees and with the help of your MS Treatment Centre (your hospital) and the technical processor both manually and on an automated basis.

When your MS Treatment Centre and the technical processor become involved, your personal data will be processed under an agreement on personal data processing to be entered into between the IMPULS Foundation Fund and the hospital (as the operator of the MS Treatment Centre) or the technical processor in accordance with the applicable provisions of the Personal Data Protection Act and other applicable regulations.

2.4. Period of Personal Data Processing

Your personal data will be processed and maintained in the ReMuS in an encrypted form throughout your lifetime because the purposes of its processing can only be accomplished through long-term evaluation

and only a monitoring of this kind can yield as much information as possible on the course of MS, effectiveness of its treatment and the needs of patients with MS.

If you revoke your consent with the processing of your personal data or after you pass on, your personal data in the ReMuS will be anonymised, i.e. the following personal data will be removed from the register: your name, surname, place of residence, personal number; the remaining data will continue to be processed and maintained in the ReMuS; nevertheless, it will no longer be possible to link the data to your person.

2.5. Securing Your Personal Data in the Register

The IMPULS Foundation Fund as well as the MS Treatment Centres and the technical processor who are involved in processing your personal data for the ReMuS protect your personal data in the ReMuS from unauthorised or random access, from their change, destruction or loss, unauthorised transmissions or from other unauthorised processing or misuse. Unauthorised persons will not be allowed to access your personal data by any means.

The IMPULS Foundation Fund also protects your personal data provided by you through the MS Treatment Centre by encrypting them in such a way so that it will not be possible to state your name, surname, personal number or place of residence during further scientific processing of your personal data in the ReMuS.

2.6. Outputs from the ReMuS

Outputs from the ReMuS will only be provided upon a specific justified request, for example, from a scientific institution, a medical insurance company, the Ministry of Health, a manufacturer of medicinal products, etc. Outputs from the ReMuS will be provided in an aggregated anonymised form (which means that no specific personal data will be provided).

A commission composed of the representatives of the IMPULS Foundation Fund, the members of a professional association (the Section for Neuroimmunology and Liquorology of the Czech Medical Association of J. E. Purkyně (ČLS JEP)) and the representatives of patients' rights organisations and public institutions operating in the field of the protection of public health will always decide on allowing access to the aggregated anonymised data.

Outside of the ReMuS, the personal data of individual patients will never be provided (i.e. it will not be possible to link the data, which have been made available, to a specific patient).

3. Processing Personal Data Exclusively on the Territory of the Czech Republic

The processing of your personal data in the ReMuS takes place exclusively on the territory of the Czech Republic; your personal data are not transferred abroad.

4. Right to Access Personal Data and Protection of Your Rights

We would like to inform you that when collecting, processing and maintaining your personal data in the ReMuS, the IMPULS Foundation Fund fully respects the protection of your rights as they are defined in the applicable provisions of the Personal Data Protection Act.

Based on the obligations defined by the Personal Data Protection Act, we would also like to inform you of your rights arising from this Act.

If you request us to give you information on the processing of your personal data, we will provide you, without undue delay, with information on what data regarding your person we are processing in the ReMuS.

If you find out or if you believe that the IMPULS Foundation Fund processes your personal data in a manner, which is in violation of the protection of your private life or in violation of the law, particularly if your personal data are inaccurate, you can:

- a) request an explanation from us;
- b) request us to rectify the situation; in particular, you can request that a correction of or an addition to your personal data is made; if necessary, these data will be temporarily blocked or liquidated upon your request.

If your request is found justified, we will promptly rectify the defective situation.

5. Your Participation in the ReMuS

The decision to grant your consent with the collection, processing and maintenance of your personal data in the ReMuS is your free and voluntary decision, which will be respected by the IMPULS Foundation Fund as well as by the staff of the MS Treatment Centre and will not have any impact whatsoever on your medical care and the course of your further treatment.

There is no remuneration associated with the granting of your consent and the provision of your personal data for their collection, processing and maintenance in the ReMuS and you will not have any direct benefit from such provision. However, the information obtained based on the processing of your personal data for the purposes described above will undoubtedly help to better understand MS, which may result in improvement of the quality of medical care for all patients with MS, including you.

You will receive a copy of this information document and the consent with the processing of your personal data for your own purpose.

Your granted consent with the processing of your personal data can be revoked by you at any time by a written notice addressed to the IMPULS Foundation Fund or possibly to your physician or by an oral statement to your attending physician in the MS Treatment Centre who will document such statement in writing. If you revoke your consent with the processing of your personal data, your personal data will be anonymised (see clause 2.4 above).

6. Ethical Aspects

Before you grant your consent to the processing of your personal data in the ReMuS, the physician of the MS Treatment Centre will be available to you and will answer all your questions regarding this register. You can contact with any other questions regarding the ReMuS (for example, the substantiation of the processing of the personal data of patients in the register, the scientific aspects of the register and the like).

The ethical aspects of the ReMuS were approved by the Ethical Committee of the If you have any doubts or questions regarding ethical matters, you can contact, the chairman of the Ethical Committee, tel.:

7. Contact Information

If you have any questions or information regarding the processing of your personal data in the ReMuS by the IMPULS Foundation Fund, please contact:

Mgr. Jana Vojáčková, MBA
Tel.: 604 232 583
E-mail: janavojackova@gmail.com

IMPULS, Foundation Fund
Kateřinská 30
128 08 Praha 2