

PATIENT'S INFORMED CONSENT

to the registration of clinical data in the idiopathic pulmonary fibrosis registry (EMPIRE)

Nature and purpose of the idiopathic pulmonary fibrosis registry – European MultiPartner IPF Registry

The **EMPIRE** registry (**European MultiPartner IPF Registry**) was created in 2014 based on a database of the registry of IPF (since 2012) as a non-interventional international multi-centric database of patients with idiopathic pulmonary fibrosis (IPF) in Central and Eastern Europe. The purpose of the registry is to assess and evaluate the incidence, prevalence and mortality rate of idiopathic pulmonary fibrosis in Central and Eastern Europe, and to establish the basic characteristics of patients with this diagnosis. Information on the ongoing treatment of patients in the aforementioned region is a valuable source of data in the registry.

The EMPIRE registry is maintained by Masaryk University in Brno (having its registered seat at Žerotínovo nám. 617/9, 601 77 Brno; company registration number: 00216224), under the auspices of the Czech Pneumological and Phthisiological Society (*Česká pneumologická a ftizeologická společnost*) of the Czech Medical Association of J. E. Purkyně. It contains the results of diagnostic examinations, information on treatment and updated information on the medical condition of patients with idiopathic pulmonary fibrosis. The purpose of the registry is to summarise the scientific evaluation of a large data set on patients with idiopathic pulmonary fibrosis. The meaning of the registry is to collect as much data as possible regarding the treatment of idiopathic pulmonary fibrosis and the subsequent detailed scientific analysis of the data.

The data from the registry are of a high value and can be used for the recruitment of new patients for new clinical studies related to the IPF therapy. Data may be consequently used by pharmaceutical companies and health insurance providers. Last but not least, the registry allows the realisation of investigator (physician) initiated studies, which are an excellent platform for clinical research into this illness.

Primary targets of the research activities

- Assessment of incidence, prevalence and mortality (biennial and overall) with regard to IPF in Central and Eastern Europe

Secondary targets of the research activities:

- Description of the basic characteristics of patients with IPF (e.g. age, sex, risk factors, etc.)

Tertiary targets of the research activities:

- Description of actual clinical practice with regard to IPF in participating countries from Central and Eastern Europe:
 - Diagnostic algorithm
 - Treatment methods and management of patients with IPF
 - Treatment outcomes (treatment response, overall survival) and quality of life
 - Use of resources
- Assessment of the number of patients suitable for participation in clinical studies.

The scope of data collected and the processing period

The operation of the registry entails the collection of clinical data from medical records kept by healthcare providers with regard to the treatment of IPF. Individual patient data collected in the registry includes sex, height, weight, month and year of the birth, race, health insurance company and name of their attending physician. In case the full date of birth and initials of the patient occurs, they will be deleted from the registry on 1st January 2019, the latest.

The results of the project, if any, will be published *en masse* for a large group of patients, not individually for each patient. The patient's identity will never be disclosed, nor will their personal data be transferred outside the provider of healthcare services.

It is a long-term retrospective registry. It is assumed that the data will be collected and processed on a long-term basis, for decades. The exact term of expiry of the data collection process cannot be defined at this point. Once any data becomes irrelevant for the purpose of research, it will be deleted immediately. The data shall remain saved in the registry, unchanged, for a period of 15 years after the termination of the registry; the identification key allowing the identification of each patient shall be destroyed by the provider of the medical services within one year after the termination of the registry.

Patient rights protection guarantee

The process of the collection of data for the registry does not entail any additional medical examination and no new and untested pharmaceuticals are used. The retroactive collection of data about the course of treatment shall not affect the current treatment.

The access to the electronic system is restricted; it is limited to the data controller and, to a certain extent, the attending physician for the purpose of data entry, based on their respective rights.

Data is processed solely upon the basis of the patient's consent with personal data processing.

Patient's consent with the processing of personal data

The registry only contains pseudonymised and anonymised data which is well protected against misuse. Data on the course of treatment is never processed without the patient's consent. We would therefore like to ask you for your written consent with the collection and processing of the aforementioned data about your treatment for research purposes. The consent is voluntary and the refusal to grant it shall have no effect on the medical treatment. You have the right to withdraw your consent at any time without giving the reason for doing so, whereupon the data regarding your treatment will be deleted from the registry.

By signing below, you agree that your provider of medical services (healthcare facility) may enter the relevant data regarding your treatment into the centralised registry for idiopathic pulmonary fibrosis (EMPIRE), and that Masaryk University (MU) may process the data for the purpose of research into idiopathic pulmonary fibrosis. Masaryk University shall be the data controller with respect to all of the data in the registry. Your data will not be disclosed to any third party.

Masaryk University and providers of medical services are obliged to act in strict compliance with the relevant provisions on personal data protection (in the case of the Czech Republic, Act number 101/2000 Coll., on Personal Data Protection, and the General Data Protection Regulation).

Masaryk University shall receive the data on patient treatment without identification data. Instead, a code is used which Masaryk University cannot decode. The provider of medical services can identify the patient in exceptional and justifiable cases where the patient's safety may be an issue. That being said, the identification data of the patient will not leave the premises of the healthcare facility even in these exceptional circumstances and the patient's identity, as replaced by the individual code, will not be disclosed to Masaryk University.

Encryption shall not affect the ability of the provider of medical services to keep the medical records and to provide treatment to you. The processing of your data in the registry does not carry any obligation on your part, nor shall it cause any harm to you. The data from the database will not be used for the purpose of the sale of goods or services. Due to the long-term nature of the data collection project, it is impossible to determine how long the data will be retained and processed via the registry. However, once the data is no longer relevant for the purpose of research, it will be deleted. Masaryk University shall not disclose the data on your treatment to any third parties.

You have the right to withdraw your consent with personal data processing at any time, with no effects on your treatment, via a simple written withdrawal notice addressed to your provider, as they are the only entity that is able to match the anonymous code and your set of data. The provider shall use their login data to delete the data retained under your code.

Furthermore, you have the right to receive information regarding your personal data retained by MU or the provider of medical services, and its purpose. Additionally, you have the right to the rectification or erasure of the data about your person. However, you will most likely receive an explanation that MU is unable to identify *your* individual data in the large set of anonymised or pseudonymised data.

You have the right to contact Masaryk University or your provider of medical services at any time. Should you have any questions regarding the processing of your data for research purposes or the measures adopted by MU with respect to the protection of your personal data, please contact the contact persons listed at <http://empire.registry.cz/>. The data on your treatment will not be transferred to third countries.

Patient declaration

I, the undersigned, born,

hereby grant my full and informed consent that my healthcare provider may collect and process the data related to the course of my treatment with idiopathic pulmonary fibrosis. I hereby acknowledge that I have read the text on the pages above and have understood the text, and that any question I might have has been answered.

By providing my signature, I hereby agree that the data concerning my treatment may be anonymised and pseudonymised by my provider of medical services and subsequently transferred to **Masaryk University**, company registration number 00216224, whom I hereby authorise to process my personal data for the purposes describe above.

I agree that the data on my medical treatment may be used for research purposes in the area of idiopathic pulmonary fibrosis and related diagnoses. I have been informed that I may request that the data controller allows access to my personal data, as well as about my right to erasure or rectification, the right to object to processing, the right to the restriction of processing, as well as the right to data portability and the right to be informed about any breach of security regarding my personal data. I am aware of the fact that I may withdraw this consent at any time or to file a complaint with the supervisory authority.

I am aware of the fact that, should I have any questions regarding the operation of the registry, I can contact my provider of medical services or directly contact the Institute for Biostatistics and Analyses, Faculty of Medicine, Masaryk University, Kamenice 126/3, 625 00 Brno, Phone: (+420) 549 494 352.

Having been instructed, I am not aware of any reason that would prevent me from granting my consent with the data registration. I voluntarily agree with the registration of clinical data in the registry for idiopathic pulmonary fibrosis of the Czech Pneumological and Phthiseological Society (*Česká pneumologická a ftizeologická společnost*) of the Czech Medical Association of J. E. Purkyně.

In dated

Patient's signature

Date

I have discussed the key issues with the patient using this document. I believe I have thoroughly informed the patient about the scope of the project, as required in accordance with the applicable ethical and legislative standards, and I shall provide the patient with their copy of the signed and dated informed consent form.

Attending physician

Date

Name and signature