European Reference Network
for rare or low prevalence complex diseases
Network Respiratory Diseases (ERN-LUNG)

Co-funded by the Health Programme of the European Union

PATIENT INFORMED CONSENT FORM

Dear Patient,

We invite you to take part in a patient registry for rare lung diseases. Participation is voluntary and requires your written consent as a legal basis to use your data. Please read this information carefully and ask your medical doctor for explanation if you have any question.

EUROPEAN REFERENCE NETWORK REGISTRIES

- Rare lung diseases are a number of rare and complex pulmonary conditions including idiopathic pulmonary fibrosis, sarcoidosis, cystic fibrosis, non-cystic fibrosis bronchiectasis, pulmonary hypertension, primary ciliary dyskinesia, alpha-1 antitrypsin deficiency, mesothelioma, chronic lung allograft dysfunction, and other rare lung diseases. Some of these result from chronic lung diseases and cause debilitating health conditions e.g CF. Diagnosing rare lung diseases may require long period of time. Moreover, approved drugs are not available in some cases.It may require multidisciplinary efforts for the management of rare lung diseases.
- ERN-LUNG is a patient-centric network of European healthcare providers and patient organisations, committed Europe-wide and globally to reducing morbidity and mortality from rare lung diseases in people of all ages through patient care, advocacy, education, research and knowledge-sharing. It provides patients with access to the interdisciplinary member teams, providing online second opinions on complex cases without requiring patients to travel. The site where patient registries are found is ERN-LUNG Patient Registry (https://ern-lung.eu/patient-registries/)
- To understand the course of a disease and investigate new diagnostic procedures and treatments in order to improve patient care, ERNs need databases (also known as “registries”) for research and knowledge development.
- To build such registries, data from many patients must be combined. We ask for your consent to include your data in the ERN-LUNG Registry to perform research, as described below, in accordance with national and European data protection laws and ethics guidelines.
- Only the data required for such research will be recorded and may be shared with users as outlined below. Such data may include age, gender, diagnosis, age at diagnosis, as well as utilization of ERN-LUNG services.
- Your data privacy will be secured as described below in this form. Only your doctor will be able to link your data to you. Therefore, the risk of re-identification by unauthorized persons is minimal.

VALUE & BENEFITS

HOW WILL THE DATA BE USED?

The data collected in this registry is used to improve the delivery of healthcare, including the diagnosis, treatment and prognosis of patients with rare lung diseases.
Research is often carried out in collaboration with other researchers. By sharing data, more questions can be answered.

Only users authorized by the **Registry Data Access Committee** can use the data. This Committee is composed of qualified health professionals, patients' representatives as well as members with legal and ethical expertise. It ensures that the request for data use aligns with the purposes of the registry and its policy.

The Registry Data Access Committee may provide data access to **clinical researchers from within or** outside ERN-LUNG**, patient organizations, and the pharmaceutical industry** in order to develop projects, policies or studies aimed to improve the delivery of healthcare for rare diseases**.** Also, registry data may be shared with **health authorities, policy makers and regulators** to inform their decisions on rare disease health policy and approval of medicines.

Data use for commercial purposes

Companies might request access to data stored in the registry to perform research aimed to develop new therapies for your condition. For example, the registry can inform companies how many patients live with a certain disease and help find patients in clinical trials of new therapies.

Typically, the results of this research will become property of the company that may also use them for further **commercial purposes** and to patent. You will not acquire any rights over these results, own them in any way, or be entitled to share any future financial benefit derived from this research.

You may choose if you want to allow the use of your data for commercial research.

Data transfers outside the EU

Data without any personally identifiable information may also be forwarded to researchers working in countries outside the EU, where the General Data Protection Regulation (GDPR) does not apply. In this case, a written agreement will be set up to ensure that the data is processed in compliance with the GDPR. You may choose if you want to allow the transfer of your data to non-EU countries to contribute to projects directly aligned with the aims of this registry within a framework compliant with GDPR.

Future changes in data collection

To gain more insight on your condition we may need additional data in the future. This information will be published on the registry website ERN-LUNG

In the event a disease-specific registry exists for your rare lung disease, more detailed clinical data will be collected. Such disease-specific registries are of great importance to better understand the precise nature of rare diseases. More information on the available registries can be found on the registry website.

Furthermore, we may request additional data from existing databases/registries, such as ERN-LUNG Registry warehouse (https://ern-lung.eu/registry-data-warehouse/) including other ERN registries. You may choose if you want to allow the linking of your data with additional data as described above.

Re-contacting to participate in research projects

In the future, research projects on the diseases and conditions covered by this registry may be proposed. You may choose if you want to be re-contacted by your medical doctor to participate in such studies. If you agree to be contacted, you are free to refuse, without any prejudice, participation in the proposed studies after you have been fully informed. Your current care will not change in any way if you choose not to give your consent.

WHAT ARE THE BENEFITS?

While there is no direct benefit from participating in this registry, the knowledge about the disease will be improved. This may benefit you and other patients suffering from the same disease.

The participants may benefit by facilitated access to clinical studies aimed to prevent and treat the disease.

Communication of research results

The results of the research will be communicated through the ERN-LUNG website, especially on the _ERN-LUNG Patient Registry website (https://ern-lung.eu/patient-registries/], and/or by the patient's medical doctor upon request, and/or publication in scientific journals where personal data are not provided. The privacy of your data will always be protected as described below.

Incidental findings

It is possible that during an investigation using data submitted to the registry an abnormality will unexpectedly be discovered that is directly relevant to your personal health or to the health of your family members. We call this an incidental finding. To make a sound choice, it is important that you weigh up the pros and cons of using this information. On the one hand, medical measures may be available that can be taken in time if the findings are known. However, there can also be disadvantages to knowing about a health risk. Especially if no effective medical interventions are available, the knowledge about potential future health problems can cause psychological distress. Some findings, such as a hereditary predisposition for a disorder, may mean that some of your family members are exposed to the same health risks.

You are asked to give your consent to be informed by your medical doctor about any incidental finding that is directly relevant to your personal health or to the health of our family members.

PROTECTION

WHAT ARE THE RIGHTS OF THE REGISTRY PARTICIPANT?

- You decide whether to participate in the registry. Please take as much time as you need to make this decision. You do not have to sign anything. You can decline participation without giving any reasons. You will receive the same treatment irrespective of whether or not you agree to participate in this registry.
- You have the right to give or withhold your consent at any time. If you consent today, you may modify or withdraw your consent later, without any prejudice. Your doctor will explain how your consent can be modified and how the data can be removed from the registry if you wish so. Please be informed that, to guarantee the validity of any research performed, data already processed cannot be deleted. However, this data will not be used in new research projects after withdrawal.

- You are entitled to receive further information about the purposes for which your data will be processed and who will have access to it. You can also request to access your data at any time.
- The hospital where you are treated is the "data controller" responsible for the **local protection** of confidential patient data. If you have any concerns about the way in which your data is processed, you would like more information or to exercise your rights, you may contact the Data Protection Officer, or you may raise a complaint to the relevant data protection authority. You can find contact details of the local Data Protection Officers at the registry website ERN-LUNG Population registry (https://ern-lung.eu/patient-registries/). They have the duty to ensure the data is processed safely and to notify you if a breach of data security occurs. Any inquiries should be addressed by the Data Protection Officer within 30 days.
- For all data submitted to the **central registry database**, the ERN-LUNG Network Coordintion Team and its principal investigator Prof. Dr. TOF Wagner is responsible for the protection of the data, its storage, use and access: ERN-LUNG Network Coordination Team - Prof Dr. TOF Wagner - Universitätsklinikum Frankfurt - Theodor Stern Kai 7 - 60596 Frankfurt am Main - Germany

HOW WILL DATA BE SECURED?

- Participation in the registry will be kept strictly confidential and all information will be handled through very secure electronic systems. As the registry involves collecting information from many centres, the system will be password protected and only persons specifically involved with the registry will have access.
- The registry users and administrators will not be able to contact you because your name, address and hospital number will not be recorded. All your patient data will be pseudonymized before being stored in the registry. This means that all identifiers that relate to you will be removed and replaced by a pseudonym. Only your medical doctor can link the pseudonym to you. Therefore, the risk of re-identification by unauthorized persons is minimal.
- In all publications emerging from the registry, it will be ensured that it is not possible to identify an individual patient, e.g., by providing data in tables or presenting age categories rather than the real age.
- A pseudonymization service will be used for this purpose. It allows to identify duplicate registration of patients, linkage between registries and other data resources, keep data protected and preserve the possibility of re-contacting by the medical doctor in charge.
- The registry data will be stored on a secure server in https://www.imi-frankfurt.de.The data will be kept in the database for at least 15 years.

COULD PARTICIPATION IN THE REGISTRY CAUSE ANY HARMS?

- Participating in this observational registry will not cause any health risks.
- Even though the registry has processes in place to ensure your personal information is protected, there is a remote risk the data could be matched with information you have already authorized in publicly available databases such as ancestry websites or public rare disease registries with identifiable information. To minimize this risk, researchers asking for access to registry data will confirm in writing not to try to identify you by any means, applying their duty of professional secret.

ADDITIONAL INFORMATION

Costs

Participation in this registry will not entail any costs for you.

Ethics Committee Approval

This Registry has been reviewed and approved under the number 20-950 by the Institutional Ethics Committee of the University Hospital Frankfurt.

If you have any other question about the registry, please contact: ERN-LUNG Network Coordination Team - Prof Dr. TOF Wagner - Universitätsklinikum Frankfurt - Theodor Stern Kai 7 - 60596 Frankfurt am Main - Germany

INFORMED CONSENT

Patient First and Last Name:……..……..……

Date of Birth (dd/mm/yyyy):: .. .. / .. .. / .. ..

ID number:……

I have read the information sheet about the ERN-LUNG

I have been given the time and opportunity to ask questions about the objectives of the registry and the use of my data and that I have solved all my doubts with the medical doctor.

I understand that my participation is voluntary and that I can withdraw the consent at any time without the need of justification and without affecting my future medical care.

I approve that my data will be stored in the ERN-LUNG, used for non-profit purposes and shared with approved users to improve the delivery of healthcare as described above.

I consent to the processing of my pseudonymized data for the purposes described above.

The following consent conditions are optional. Please indicate your preferences by writing your initials in the relevant box. If you leave the boxes empty, we assume you agree to the statements.

YES	NO	
		I CONSENT that my pseudonymized data may also be **used to support commercial projects** aimed to improve healthcare.
		I CONSENT that my pseudonymized data **may be transferred to non-EU countries, in compliance with GDPR,** to support projects aimed to improve healthcare.
		I CONSENT that my pseudonymized data may be **linked to existing databases/registries** to improve healthcare.
		I WOULD LIKE TO BE CONTACTED by my medical doctor about any **research project and/or clinical study related to my condition.**

		I WOULD LIKE TO BE INFORMED by my medical doctor **about any incidental finding** that is directly relevant to my personal health or to the health of my family members.

PATIENT Date and Signature:	**MEDICAL DOCTOR / AUTHORISED WITNESS** Full name: Position: Date and Signature:

Please keep one copy of this Informed Consent Form in case records and hand one copy to the person who has signed this form.