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

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Information for ERN-LUNG patients

ERN-LUNG is a Network of European Healthcare Providers (HCPs) dedicated to ensuring and promoting excellence in care and research for the benefit of patients affected by rare respiratory diseases in all the member states. The purpose of the ERN-LUNG Registry is to measure, survey and compare distinct aspects of Rare Diseases manifestation, course and treatment, and especially to gather information on the quality of care within ERN-LUNG. The effort needed to gather registry data is enormous and yet worthwhile since they are the basis for new knowledge based on facts instead of assumptions.

The ERN-LUNG Registry is part of the European Reference Network for Rare Respiratory Diseases ERN-LUNG. We follow the recommendations of the EU Expert Committee on Rare Diseases including the international interoperability of registries and databases to pool and exchange knowledge and data on rare diseases.

Why do we need the ERN-LUNG Registry?

Registries are the only way to pool data in the field of Rare Diseases (RD) in order to achieve a sufficient sample size for all kinds of research questions. RD Registries such as the ERN-LUNG Registry constitute key instruments to develop clinical research in the field of RD, to improve patient care and healthcare planning. ERN-LUNG is the European Reference network for Rare Diseases of the Respiratory System. In this patient centric and multi-professional network experts from all over Europe work together in the attempt to improving speed and quality of the diagnosis, care, treatment, and the prognosis of rare pulmonary diseases. For the evaluation of the quality of services provided by ERN-LUNG it is important to know which patients are cared for in the network. For knowing this and comparing these data over time to detect improvements, strengths and weaknesses we have developed a very lean data collection within the network. This is a ERN-LUNG specific data collection across the whole spectrum of rare lung diseases covered by this network.

Why should I as a patient participate?

Patient involvement is the key factor in the establishment of any patient registry, especially RD Registries. For the purpose of the above aims, we need as many patients in the ERN-LUNG Registry as possible in order to make sure that data are representative of the whole spectrum of the diseases we cover in ERN-LUNG and to have enough patients to compare groups of patients with each other. To make sure we not only collect your data but also make the best possible use of it we have a patient representative on the Governing Board of the ERN-LUNG Registry. He reports to the ERN-LUNG Patient Board about all activities related to this Registry.

Which data are collected?

We collect demographic data (e.g. age at onset of the disease and age at diagnosis, an gender) but also data on where you are cared for and whether you or your treating Doctor has ever utilized any of the ERN-LUNG services for you. Additionally, it gathers data on how the patients received cross-border care provided by ERN-LUNG (via cross-border referral, EXABO or CPMS). The data is collected using a

common set of definitions, following the recommendations of the EU Expert Committee on Rare Diseases. This ensures international interoperability of registries and databases to pool and exchange knowledge and data on rare diseases.

Ways to register

Registration will be performed by the treating physician via password-secured access. The access authorization will be passed on a personal basis by the ERN-LUNG Registry administrator.

Information about data security

To ensure that patients are not accidentally registered twice and to take into account a changing of caring physician, personal data such as first name, last name, date of birth, and optionally middle name and place of birth have to be included in the first step of patient registration. These will be directly transferred into a Patient identification-Code (PID) and a pseudonym generated. Tracking a patient's identification with the PID is impossible. The registry administration uses the Mainzelliste,[1] a web-based pseudonymisation service of the first level, which enables the Patient identification-Code (PID) from personal identifying data. The medical health data is linked to the patient identification code (PID) and then stored in a central medical database in a data center physically separated from the Mainzelliste server used for PID generation. Personal identifying data and personal medical health data are always stored separately. While the person who registers your data retains and safely sores the list linng the personal identifying data and the pseudonym, the Registry only receives your personal medical data together with the pseudonym. The only way to trace back data form the registry to an individual will be possible for the person who registered your data.

Data saving underlies the regulations for data security laws and the medical confidentiality (GDPR). International regulations for good clinical practice (GCP) always apply. Unauthorized third parties will not have access to registry data.

Inclusion criteria

ERN-LUNG recruits all subjects diagnosed and/or treated within its Network, i.e. these are patients with the diagnosis of a rare disease of the respiratory system. Patients who do not have a respiratory RD diagnosis may be eligible if they are undergoing work-up by any member of ERN-LUNG. These patients then will be registered as undiagnosed patients.

Ethics and Patient Confidentiality

Obtaining the necessary patient consents is a prerequisite for entering data in the ERN-LUNG Registry. A template for Patient Informed Consent will be provided.

[1] Mainzelliste publication: Lablans, M., Borg, A. & Ückert, F. A RESTful interface to pseudonymization services in modern web applications. BMC Med Inform Decis Mak 15, 2 (2015). https://doi.org/10.1186/s12911-014-0123-5.

Patients can only be entered into the ERN-LUNG Registry once you have received their signed, informed consent to do so. Please store all the consent forms that your patients have signed safely at your local institution. It is the responsibility of the reporting centre to have the acquired permissions to export/report data to the ERN-LUNG Registry.

Data Security

Due to data protection regulations, the data stored in the server of the ERN-LUNG Registry must be anonymous (i.e. the patient must not be identifiable). Therefore, the authorised operator has to keep a logbook with the identifying patient data and the code generated by the registry software. It is your responsibility to make sure that access to this list of names and matching patient codes is restricted to authorized personnel only. Furthermore, please note that if he local list of matching codes and full names is lost, it will be impossible to retrieve the data identification by means of the ERN-LUNG Registry software. Moreover, data are encrypted (i.e. not de-codable) when transmitted. The ERN-LUNG Registry is protected according to EU Data Protection legislation, both physically and technically, and backup is secured.

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About us

The ERN-LUNG Registry has been designed and established by the Medical Informatics - University Hospital Frankfurt am Main consortium headed by Thomas Wagner, University Hospital Frankfurt am Main, Germany and is part of the European Reference Network on Rare Respiratory Diseases ERN-LUNG. For more information, please contact the ERN-LUNG Registry administrator by writing an Email to registry@ern-lung.eu.

Impressum

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