Information sheet

Cystic Fibrosis registries collect clinical information about people with cystic fibrosis (CF). They are used in many countries throughout the world to support medical research and to improve the care and treatment of the disease. We are establishing / have established (*include what is applicable)* a CF registry in our centre (*centre name*) in (*city, country*) and we ask your consent to include your data. The data collected in our CF centre will be sent pseudonymised, once a year, to the European Cystic Fibrosis Society (ECFS) Patient Registry ("European Registry").

Why is the collection of data important?
As CF is a rare condition, collecting data about the disease from as many people with CF as possible will allow the European Registry to measure, survey and compare aspects of CF and its treatment in a large number of people. The results will reflect the situation of CF across Europe, give us better insight into the disease, and aid medical staff and policy makers to plan and support care. Your participation in the CF Registry of (*centre name, city*) and the European Registry will be of great value.

What is the ECFS Patient Registry?
The European Cystic Fibrosis Society (ECFS) is an international community of scientific and clinical professionals committed to improving survival and quality of life for people with CF through the promotion of high-quality research, education and care. As part of the ECFS, the European Registry collects data from people with CF in Europe, to give us a deeper understanding of the disease, to facilitate the introduction of new standards of care, to provide data for epidemiological research, and to support public health-planning.

What data do we collect?
Personal data such as year and month of birth, sex, information relating to diagnosis (genotype, sweat test and other relevant diagnostic information) is collected at enrolment in the Registry. Clinical data, (lung function, weight and height, infections, treatment, complications and transplants) is collected for every calendar year. The same definitions and ways to represent the collected data elements (variables) are used by all centres and national registries participating in the European Registry to ensure the information is comparable from country to country

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For specific research projects, additional clinical data may be collected and processed when the research purpose is in line with the purpose of improving research to deepen the knowledge of CF.

How do we collect the data?
The data is collected on a centre level with a secure, web-based software system. This system was developed specially to collect data from people with CF data, and it is made available by the European Registry to approved CF centres. Once a year our CF centre sends the collected and pseudonymised data to the European Registry through this secure software.

Who can identify me?
A unique patient identifier (ID), which is a random numeric code, is generated by the software when a

patient is included in the system. Patient demographic and clinical data linked to this unique ID will be sent through the software system to the European Registry. The European Registry is not able to identify you; only your clinician or other authorised medical staff in your centre can do this. Using a unique identifier that replaces information that can identify a person is called “pseudonymisation”.

What are my rights and how do I exercise these rights?
Participation in our centre (*name, city*) Registry and the European Registry is voluntary. The decision to participate or not does not have any influence on the medical care that you receive. You have the right to withdraw your consent at any time without stating a reason, and the right to access your personal data, in accordance with the European General Data Protection Regulation (GDPR) and national legislation on data protection & information security. Please consult your clinician if you would like to withdraw your consent or exercise your rights. Your clinician will need to contact the European Registry to inform them about your decision; the European Registry will then take the necessary action (as explained above the European Registry cannot identify individual patients in the database). If you withdraw consent for your data to be collected and used as described in this document, your data will be removed from the current year and will not be collected in the future but will not be removed from previous years. This is to ensure the continuity and preservation of the data in the European Registry, which is essential to support medical research. It is not possible to exercise your right to change, delete, restrict the processing of data or the right to data portability (i.e. use your data across different services) if the data have been published.

If you believe that your rights have been infringed, you have the right to lodge a complaint with the supervisory authority. For the European Registry we advise you to contact the Coordinator, www.ecfs.eu/projects/ecfs-patient-registry/contact.

How is the data used?
The data will be used:

- To contribute to the results of analyses and comparisons of demographic and clinical outcomes of CF in (*country name*) and across Europe in the European Registry’s Annual Data Reports and At-a-glance Reports;
- To contribute to scientific research. Researchers, patient organisations and commercial companies can apply for data to use in specific projects. A formal application needs to be submitted, which will be considered by the European Registry’s Scientific Committee according to a rigorous procedure.
  Data will only be released for research or commercial purposes if there are direct treatment benefits for the people with CF and if all ethical requirements have been met;
- To monitor and evaluate if and how care is improving;
- To identify new trends, i.e. an increase in a new infection or complication;
- To help plan current and future services for people with CF;
- To prepare the landscape for clinical trials on new therapies;
- To monitor the effects of new licensed therapies when these become available;
- Anonymously (the data cannot be linked to an individual) to contribute to a future global CF registry.

The use of any information from the European Registry requires the approval of a Steering Committee, which consists of elected CF specialists representing the countries across Europe, a patient representative, and a data-controller (the person who is appointed by the ECFS to ensure the data is handled in adherence with the European GDPR). More information about the approval process can be found on the website www.ecfs.eu/projects/ecfs-patient-registry/data-request-application.

Who can access the data?
Data access is restricted to authorised users only. If authorised, your doctor or other medical staff can access the data-collection system to enter and modify data. In order to fulfill the purposes of the European Registry the following people will also have access to your pseudonymised patient data:

- The European Registry statisticians: to validate and analyse the data;
- The European Registry Service Desk: to provide support to the centres and national registries on data, software and technical issues;
- The software company: to maintain, protect and improve the database software and to solve software issues.

The European Registry's database is hosted on a secure webserver, in a reserved location, in Europe.

The European Registry may visit centres to verify that the informed consent of the patient or his/her legal guardian(s) has been obtained in accordance with local and European legislation and that the collected data matches the information in the patient medical record. Only authorised people from the European Registry, who have signed a confidentiality agreement with the centre, will be given access to the information.

How long will we process your data for?
Your data will be processed for as long as the European Registry exists. If the European Registry closes, your data will be returned to (*centre name, city*) upon request, or alternatively destroyed.

You will find more information on www.ecfs.eu/ecfspr and www.ecfs.eu/ecfspr/privacy-notice.

Informed Consent form

Dear Patient, dear Parent(s) / Legal Guardian(s),

Your centre (*name*) in (*city, country*) and the European Cystic Fibrosis Society (ECFS) Patient Registry ("European Registry") collect data from people with CF in Europe to measure, survey and compare aspects of CF and its treatment, to deepen the knowledge of the disease, provide data for epidemiological research, encourage new standards of care, and facilitate public health-planning.

Your centre in (*city, country)* and the European Registry invite you to participate in this important research project and ask your **explicit consent** to collect and process your personal data for the above-mentioned purposes. Your centre in (*city, country*) and the ECFS will each act as independent data controllers of your personal data. This means that we need your consent for both registries.

Your participation in the CF Registry of (*centre name, city*) and the European Registry is voluntary. You have the right to withdraw your consent at any time, without stating a reason, and the right to access your personal data. If you would like to withdraw your consent or exercise your rights, you should consult your clinician. The European Registry will not process any of your personal data in the future, but they will maintain the data collected before your withdrawal of consent as those data have already been used for scientific research and have been published; deleting the data may affect the purpose of the research.

The data in the European Registry is pseudonymised, which means that identification is not possible without additional information. The European Registry is not able to identify you, only your clinician, or other authorised medical staff in your centre can do this.

The European Registry may visit centres to verify that the informed consent of the patient or his/her legal guardian(s) has been obtained in accordance with local and European legislation, and that the collected data matches the information in the patient medical record to ensure the quality of the data. Only authorised people from the European Registry, who have signed a confidentiality agreement with the centre, will be given access to the information.

In the future, your data may be included in a global registry and used for additional research projects. For scientific purposes personal data may be processed outside Europe. The necessary precautions will be taken to safely process your personal data. If you believe that your rights have been infringed, you have the right to lodge a complaint with the supervisory authority. For the European Registry we advise you to contact the Coordinator, www.ecfs.eu/projects/ecfs-patient-registry/contact.

Data will be processed as long as it is necessary to improve the research on CF.

Information about the processing of your personal data in your country and by the European Registry is available on the websites (*website address of your registry]*) & www.ecfs.eu/ecfspr. If you have any questions about the use of your data please contact the Registry of (*centre name*) at *(contact details)* and/or the European Registry at www.ecfs.eu/projects/ecfs-patient-registry/contact.

Please read this document and the information sheet carefully before you decide to participate. If you agree to participate, please complete the information below as indicated.

We thank you for your support.

☐ I agree that my data is used in the CF Registry of (*centre name, city, country*).

☐ I agree that my data is used in the European Cystic Fibrosis Society Patient Registry (ECFSPR).

Name of the patient (parent / legal guardian): ……..

Signature of the patient (parent / legal guardian): ……

Date: ……

Name of the patient (parent / legal guardian): ……..

Signature of the patient (parent / legal guardian): ……

Date: ……

Signature of CF clinician: ……

Date: ……