Privacy Notice

The goal of this Privacy Notice is to explain how the **European Cystic Fibrosis Society Patient Registry (ECFSPR)** processes your personal data and how we apply the data protection principles as defined by the General Data Protection Regulation (GDPR).

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1. Introduction

The **EU General Data Protection Regulation (GDPR)** (*Regulation 2016/679/EU*) came into force on 25 May 2018. It is a first step towards giving EU residents more control over how their personal data are used by organisations. The GDPR focuses on accountability, transparency, protection and reliability, and aims to reduce the collection of data from residents without their knowledge and without transparency.

The **Patient Registry** is part of **the European Cystic Fibrosis Society** (ECFS), the legal organisation that is the **controller of the Registry data**. On a national level the centres and national registries that collect data and send data to the Registry are the data-controllers of their centre or national registry data.

The Registry collects, stores and processes pseudonymised data of people with CF who explicitly give consent to their local clinical team or national registry to register and send their data to the ECFSPR.

The Registry is committed to protecting the privacy and personal data of CF patients by complying with European Regulation, and to ensuring that any third party or processor of the data also complies with the GDPR and is contractually obliged to confidentiality.

2. What types of data do we collect?

The ECFSPR collects 'pseudonymised' demographic and clinical data from people with Cystic Fibrosis (CF) in Europe and neighbouring countries. **'Pseudonymised'** means that the ECFSPR cannot identify individual patients. Identification of patients is only possible by the centre that provides that data to the ECFSPR (directly or via the national registry) where the patient is treated.

Between the Registry and the participating national registries and CF centres there is an agreement about the **criteria of inclusion** of CF patient data in the Registry, the **type of variables** and the **definitions** of these variables. Using the same variables and definitions is essential to compare data across countries.

The categories of **data** collected by the ECFSPR are:

1. **Identification data:**
    - centre code (assigned by the software)
    - patient code (assigned by the software)
    - month/year of birth
    - gender
    - year of follow-up
    - status of the patient (alive/deceased, not seen in the follow-up year, lost to follow-up)
    - cause and date of death

2. **Health data as per the following categories:**
    - Diagnosis
    - Genotype
    - Therapy
    - Complications
    - Microbiology

- Lung function and Nutrition
- Transplant

The complete list of inclusion criteria, variables and their definitions can be found here.

3. How do we collect your data?

The Registry commissioned the company OpenApp to develop and maintain the dedicated data-collection **software ECFSTracker**. **OpenApp is a data processor**, since they process personal data on behalf of the data-controller ECFS, and is obliged to adhere to GDPR.

The data from the participating national registries and CF centres is collected in two ways (see Figure 1):

1. **Manual data-entry':** CF centres input data manually in the data-collection system ECFSTracker;
   - once a year in the Patient Annual Summary data;
   - at each patient visit in the Encounter data. Once a year the data is collated into the Patient Annual Summary.
2. **Uploading a data file:** national registries, that use their own data-collection software to collect national data, will extract a file with the information required by the ECFSPR. Once a year the file is uploaded into ECFSTracker and sent to the ECFSPR.

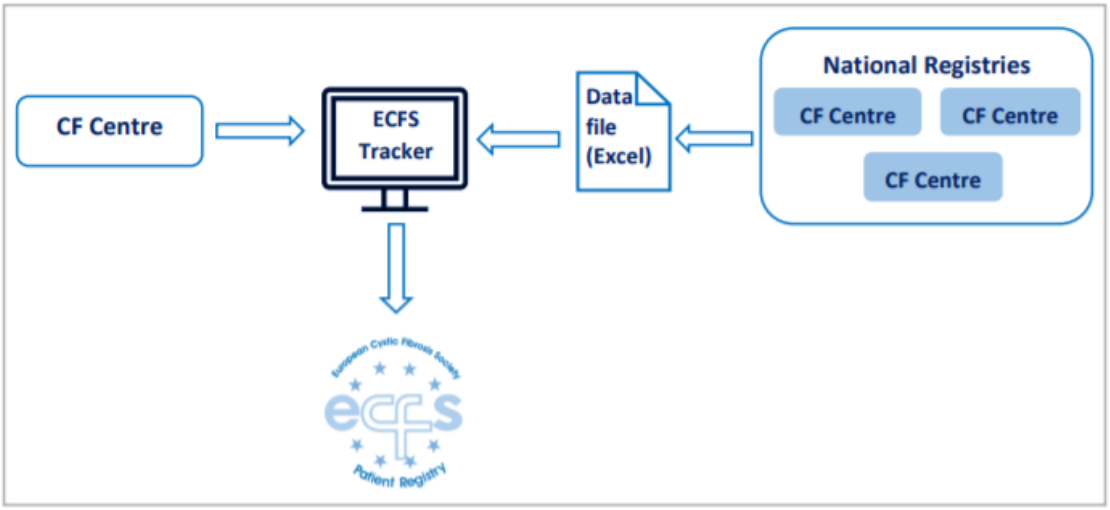

Figure 1: *Overview of how data is provided by the participating countries to the Registry.*

4. How will we store your data?

The data is stored on a secure webserver located in Germany, hosted by the company Hetzner, a **subcontractor of OpenApp**. Hetzner is, therefore, a **subprocessor of the Registry patient data**, since they process personal data on behalf of the data-controller ECFS. Access to the webserver is restricted to authorised personnel only.

Data storage complies with the European data-protection regulations and is approved by the Danish Data Protection Agency.

The ECFS plans to maintain the ECFSPR database for the foreseeable future and keep/store the data as long as the Registry is active. All information on data storage and security can be found here.

5. Who has access to the data?

Data access is restricted to authorised users only. Your doctor, other medical staff, or the national Registry data-manager can enter and modify data.

In order to fulfill the Registry's purpose, **recipients other than the controller and processors** have access to the pseudonymised patient data. These other recipients are compliant with the GDPR:

- **Statisticians (University of Milan, Italy):**
  - The statisticians in charge of **data management and data analysis** can access the European database but **cannot identify patients** by centre. When the statisticians need clarification on the data this is done through the Service Desk, the "trusted third party" and the liaison between the statisticians and the centre.
  - The statisticians download a copy of the data to a secured space on the server hosted by the university, to check, validate and analyse the data. Strict data protection and security measures are in place. The **University of Milan** is therefore a **data processor**.
- **Service Desk**: The Registry Service Desk personnel are the "trusted third party", which means they can link the centre code to the centre name. This is necessary in order to provide support to the centres and national registries for data, software and technical issues.
- **Data Quality Manager**: The Data Quality Manager is also part of the "trusted third party", to link the centre code to the centre name. This is necessary to prepare and execute visits to the centres to validate the data at source, in order to ensure high quality data.
- **Participating countries:** authorised users in the **centres and national registries** can add and correct patient data. Each centre or national registry can only access their own centre or national registry data.
- **Country Coordinator:** Each participating country has the possibility to appoint a Country Coordinator to represent the country in the Registry Steering Group. In the software ECFSTracker, the Country Coordinator has the opportunity to view the pseudonymised data from the centres in the country, which is useful to oversee the dataflow, and to create and present country reports at national meetings or to the government.

6. How is the data used?

The data is used to **measure, survey and compare aspects of CF and its treatment** in the participating countries with the aim to deepen our understanding of CF, improve standards of care, provide data for epidemiological research and facilitate public health planning.

The results are published in Annual Data Reports with demographic and clinical outcomes across Europe.

Scientific research is conducted: researchers, patient organisations and pharmaceutical companies can apply for data, following a formal **procedure** (for more information please click *here*), to:

- Use the data for **epidemiological research** and prognostic analyses to forecast trends in CF. More information and examples on epidemiological research can be found here.
- Prepare the landscape for **clinical trials** (e.g. mapping the number of CF patients with a specific mutation across Europe) and specific research studies. More information can be found here.
- **Monitor the safety and effectiveness of new CF treatments**.

It is the Registry's policy to provide only aggregated data in tabular format. In exceptional cases, and at the Registry's discretion, when the research objective is of interest to the Registry, raw data may be released.

7. What is our legal basis to process patient data?

Organisations that collect and use personal data must have a lawful basis for doing so under the GDPR and they are obliged to inform you. These are the lawful bases on which the Registry relies to process personal data:

- Your **explicit consent** to use your data for the defined purpose, which is to measure, survey and compare aspects of CF and its treatment in the participating countries with the aim to deepen our understanding of CF, improve standards of care, provide data for epidemiological research and facilitate public health planning.
- **Archiving purposes in the public interest**, scientific or historical research purposes or statistical purposes.

The Registry collects data from patients who have given their **explicit consent** to their local clinical team or national registry to register and send their data to the Registry. It is the responsibility of the participating countries to ensure that their local informed consent is GDPR compliant. We are currently updating the Informed Consent form, developed by the Registry, to comply with the GDPR regulations and which can be used by the individual centres. The informed consent should be checked with the local data protection authorities and translated into the local language.

In some countries, e.g. Sweden, data is collected for all patients according to their National Policy on Data Registries and Epidemiologic Research. Exceptions are made for those patients who **explicitly deny access** (Opt-Out).

All participating countries are obliged to provide the Registry with a copy of the approval from their **Data Protection Authority**, preferably the national Data Protection Authority, to collect patient data and export the data to the Registry. In addition, the participating centres and national registries must provide the Registry with a copy of the approval from their **local Medical Ethical Committee** to collect patient data and to export to the Registry.

8. What are your rights as a patient?

The right to access, change and delete personal data and to withdraw consent.

Every patient has the right **to access his/her personal data**. This includes the right to ask if the Registry processes personal data about you, to obtain a copy of this personal data and to obtain additional information such as which personal data the Registry processes about you and for what purpose, with whom this personal data is shared, how the personal data is collected, and how long the personal data is kept.

Any patient whose personal data is processed has the right **to correct incomplete or erroneous information** and **to request the removal of his/her personal data**. If the patient wished **to withdraw his/her consent** to use his/her data for the Registry, he/she needs to contact the local CF centre to discuss the request. The local clinical team will need to inform the Registry Service Desk (servicedesk@ecfregistry.eu) in writing to delete the data. The Registry will ensure that the patient's data is removed from the current year and that it is not be included in future years in the European database. It is not possible to remove the data from the previous years since those data already have been published.

The right to lodge a complaint with a supervisory authority.

Every individual has the right to lodge a complaint with the supervisory data protection authority. For the ECFS this is the **Danish Data Protection Authority**, **Datatilsynet.**

We advise you to first contact the Registry Coordinator via ecfs-pr@uzleuven.be or tel. +32 484 443 435.

9. Changes to our privacy policy

The Registry may occasionally amend this privacy notice. We announce changes via our website. This statement is valid from 25/05/2018.

10. How to contact us?

Queries about how the Registry protects patient data should be directed to the **Data Protection Office,** ecfs-pr@uzleuven.be.

The data controller, as required by the Data Protection Act, is ECFS, based in Denmark, Kastanieparken 7, 7470 Karup, and is represented by Dr Valérie Storms, a CF patient representative for CF Europe. Morfe information about the ECFS Privacy Policy you will find *here*.

11. How to contact the appropriate authorities?

Our Supervisory Authority is the Danish national authority on data privacy, Datatilsynet.