

UK Cystic Fibrosis Registry Information for patients (aged 16 years and over)

You are being invited to take part in a project to maintain a patient registry (the CF Registry) for people with Cystic Fibrosis (CF). You are being invited to take part because you have cystic fibrosis. Before you decide whether to take part, it is important that you understand why this project is taking place and what it will involve.

Please take time to read the following information carefully and talk to others about it if you want to. You can also ask us if there is anything that you do not understand or if you would like any more information. Take time to decide whether or not you wish to take part in this project.

What is the CF Registry?

The CF Registry records and analyses information about the health and treatment of people with Cystic Fibrosis in the UK. It also records the number of people in the UK with CF and where they are. The information is held on a secure and confidential computer database. The CF Registry is paid for by the Cystic Fibrosis Trust.

Why have a CF Registry?

CF is a complicated condition that affects a relatively small number of people. By bringing together and analysing the information on all of them, we can understand better the different things that affect people with CF and how different treatments affect them. Doctors can learn from this and provide better care for people with CF in the future.

What information is kept in the CF Registry?

The information kept in the CF Registry is similar to the information that is recorded during a visit to your CF Centre or Clinic: height, weight, lung function tests, respiratory cultures, x-ray results, and the results of other tests carried out at the hospital. The CF Registry also holds information about the treatments you are given and the drugs you are taking, along with details of any complications you may have. The Registry also records the name of your genotype. A genotype is part of a person's genetic makeup, which controls a particular characteristic. In cystic fibrosis, a person's genotype tells us about the severity of their condition, and, in some cases, which treatments will work for them.

Do I have to take part?

It is up to you whether or not you decide to take part in the CF Registry. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form.

Your care will not be affected in any way if you decide not to take part.

Can I change my mind later?

If you agree to take part you will be able to withdraw from the CF Registry at any time in the future without giving a reason. If you withdraw your consent to taking part, any personal information held about you will be removed from the CF Registry and a record will be kept that you withdrew consent to taking part.

Your care will not be affected in any way if you change your mind and withdraw from the CF Registry.

How is the information collected and what is it used for?

The information is taken from your medical notes that are written by the care team whenever you visit the hospital or when they visit you at home. They will enter it into the CF Registry at the hospital and they will be able to use it to follow your progress and get an overall picture of everyone with CF at your Centre.

The information from all the CF Centres and Clinics will be used to get an overall picture of the number of people with CF in the UK, the state of their health and where they are treated. We will then be able to see if there is a difference between the health of people in different hospitals and different regions of the UK. We can then look at the reasons for any differences and use them to make improvements to the care of people with Cystic Fibrosis.

The CF Registry will produce an Annual Report each year that summarises this information and which will be available on the Cystic Fibrosis Trust website. We will also be able to compare the health of people with CF in the UK to the health of people with CF in other countries.

Information from the CF Registry will be used for planning future services for people with CF in the UK. The CF Registry will also be used to identify trends that may not be obvious in one hospital, for example if new infections are emerging, and to identify groups of patients who could take part in research studies and clinical trials. All of these will contribute to improving care for people with Cystic Fibrosis in the future.

We also use Registry data to monitor the safety of medicines that are made by pharmaceutical companies. This involves the Cystic Fibrosis Trust producing reports based on Registry data that are used by the medicines regulator to assess the safety of cystic fibrosis medicines. The pharmaceutical company also sees these reports. No patient level information, or any information that could identify individuals, is

included in these reports. Patient level data, even in anonymised form, is never given to Industry by the UK CF Registry.

The Cystic Fibrosis Trust is planning to maintain the CF Registry for the foreseeable future and will keep the data indefinitely.

The UK CF Registry has a website, which can be found at www.cysticfibrosis.org.uk.

Will my information be confidential?

All the information in the CF Registry is held confidentially. The CF Registry is compliant with Data Protection legislation and has Research Ethics Committee approval. It is managed in accordance with relevant laws and ethical guidelines.

The CF Registry needs to hold information that can identify you (name, date of birth, and postcode) so that your own hospital can enter the information and use it to monitor your care and to ensure that your information is not recorded more than once. This information is used to generate an anonymous number so that you cannot be identified when the information from each clinic is brought together to give the overall picture of CF in the UK.

A very small number of experienced staff (these are referred to as 'trusted third parties') will also be able to see your personal information. This is to enable the information to be analysed and the system maintained, and is in accordance with Data Protection legislation.

We would also like to follow your health status by utilising information collected by the NHS and the Office of National Statistics. To obtain this information we will need to disclose your date of birth and National Health Service number; these details will be treated in confidence and in accordance with the Data Protection legislation.

The use of any information from the CF Registry will require the approval of the CF Registry Steering Committee comprising Specialist CF clinicians, representatives of the Cystic Fibrosis Trust and other specialists, including a patient and parent. Information that can identify you personally will NEVER be given to anyone other than those outlined above, or published by the CF Registry.

The Data Controller is the Cystic Fibrosis Trust. If you have any questions about the use of your data, if you want to make a complaint or if you want your information removed from the registry, please contact the CF Registry Lead at the Cystic Fibrosis Trust, 1 Aldgate, London, EC3N 1RE.

Cystic Fibrosis Trust

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Thank you for taking time to read this information sheet and for considering taking part in the CF Registry. If you have any questions or require any further information please talk to a member of the care team at your CF Centre or Clinic or contact the CF Registry at the Cystic Fibrosis Trust on 020 3795 2180.