

Sample Patient Information Sheet:

Please check with your local Data Protection Agency before using to obtain patient consents.

Cystic Fibrosis Registry Patient Information Sheet

Registries containing clinical information about people with cystic fibrosis (CF) are used in many countries throughout the world to help with medical research and improve the care and treatment of patients with CF. We are setting up such a CF registry for our country and are asking your permission to include your data. There are also plans to create Europe-wide and global registries for CF patients that will share anonymised data from many countries in order to give us even better information on how to improve the treatment for CF.

All information available from our national registry will be anonymous. Similarly, it will not be possible to identify specific individuals from the European or global registries.

Your own hospital team will enter your data and keep it up-to-date and may use it to follow your progress. However, any information that could allow you to be identified will be removed from the data held in the national and European registry. Very strict controls will be put in place to make sure you cannot be identified from the national or European registry.

Apart from your local clinic team, trusted third party/parties will also be able to identify you if required to do so on a strict need-to-know basis. This is necessary to make sure that the registry works efficiently throughout Europe as well as to ensure that your anonymity is safeguarded by releasing data for research only according to national and EU laws and carefully monitored procedures. The trusted third party may sometimes also be asked by your local hospital team to help them by entering data into the registry in order to get it up-to-date.

Data from the Registry will have many uses. A few examples of these are:

- To measure the performance of your particular clinic as well as your particular country against that of other CF clinics and other countries both in Europe and across the world
- To judge which treatments are of greater benefit and how care is improving
- To identify new trends, for example an increase in a new infection or complication
- To provide information for planning future services for people with CF
- To identify patient groups who could be approached to take part in particular research studies. Contact for this would only come through your local CF clinic
- Data will only be released for commercial purposes if there are direct treatment benefits for patients with CF and if all ethical requirements have been met

The use of any information from the European registry will require the approval of a Steering Committee. This will be made up of elected CF specialists from across Europe, representatives from other world registries with whom we are working to fight the disease (e.g. the US), the trusted third party and a data protection legal and ethics expert to safeguard the use of your data. If the Registry closes, your data will be returned to your local clinic team if requested by them, otherwise it will be destroyed.

Your participation is entirely voluntary and you have the right to withdraw at any time without stating a reason.

The Data Controller is your local hospital and the European Cystic Fibrosis Society (ECFS) for the European Registry. If you have any questions about the use of your data, or if you want your information removed from the registry, please contact your local clinic team.