

Cystic Fibrosis strength in numbers

Working with industry to make medicines safer

New drugs and safety

Once new drugs have completed [clinical trials](#) and been licenced for use in the NHS, the pharmaceutical companies that manufacture them are required to monitor the long-term safety of the drug in everyday practice, usually over a five-year period. These are known as, 'pharmacovigilance' or 'drug safety' studies – they're the same thing.

There are various ways of organising these drug safety studies, but there are several key advantages to using a disease registry such as the UK CF Registry:

- **a) Quality of data:** In any study looking at the safety of drugs, it is important that the data collected is as accurate and as complete as possible. The UK Cystic Fibrosis Registry has a whole range of procedures to ensure the accuracy and completeness of data.
- **b) Quality of the study:** By using the UK CF Registry it is possible to monitor outcomes in the group of patients being prescribed the drug. These outcomes can be compared to those in patients not taking the prescribed drug. This helps make it clear whether any observed effects are likely to be connected to the drug, or not.
- **c) Independence:** The European Medicines Agency is keen that drug companies use independently run disease registries. For CF drugs, this means NHS CF doctors and UK CF Registry statisticians conducting the analysis, as well as providing input to the study design, and interpretation of results. **This means that summary data only (no patient level data relating to individuals) are provided to the pharmaceutical company.** It also ensures the results of the analysis are agreed by experts who do not work for the company.

Which drugs?

Which companies to work with is driven by the potential benefits to patients of the drugs coming to market. These decisions, and the development of agreements with the companies that safeguard the integrity of the Registry and the anonymity of the data, are made by the CF Registry Steering Committee, chaired by Dr Siobhán Carr.



Costs

Each company pays the full costs of their study. The income received by the Trust for providing this service helps to support the running costs of the Registry, and provides an annual Registry Support Grant to each clinical centre to support the time spent inputting data to the Registry. This benefits the whole community. You can find more about how the Registry benefits people with cystic fibrosis at cysticfibrosis.org.uk/registry.

This can only strengthen commitment from the centres, improve the quality of data on the Registry and help provide security for the future.

For more information, please contact the Registry team by emailing registry@cysticfibrosis.org.uk.

Working with industry

The Cystic Fibrosis Trust works with several companies wishing to use results from the Registry to conduct their long-term safety studies, after the introduction of new therapies.

The main objectives of this work are:

- to improve the quality of long-term safety studies of new medicines;
- ensure that patients gain access to new drugs, which have been through a rigorous safety assessment; and
- secure funding to help in the running costs of the Registry.

Looking at the bigger picture, the Cystic Fibrosis Trust is leading the way in producing a 'template of good practice' for working with industry in monitoring the safety of new drugs. This template, or model, will be of great interest to other charities, government and the NHS.

The UK CF Registry

The UK CF Registry, including its drug safety study programme, is approved by the NHS Health Research Authority's Research Ethics Service. The UK CF Registry is compliant with General Data Protection Regulation. 99% of people with cystic fibrosis in the UK have consented to their routine clinical information being entered onto the UK CF Registry.

All CF centres participate in England, Wales, Scotland and Northern Ireland, which add information from approximately 10,000 people with CF onto the secure Registry portal each year.

For more information about the Registry, visit cysticfibrosis.org.uk.

Uses of the Registry



Helping people with CF and their families understand cystic fibrosis, and make informed decisions.



Giving clinical teams the evidence they need to improve the quality of care.



Monitoring the safety and effectiveness of new treatments for cystic fibrosis.



Providing data for research to find out the best ways of treating and beating cystic fibrosis.



Helping commissioners provide funding to NHS CF centres that is proportionate to their patients' disease severity.

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