

Application for data from the Cystic Fibrosis Registry of Ireland (CFRI)

Introduction:

The CF Registry of Ireland has collected demographic and clinical data from consenting cystic fibrosis (CF) patients in Ireland since 2002. Over 90% of the people with CF are on the registry, and each year the number of people with CF increases. In 2018, over 1,200 people living with CF in the Republic of Ireland were on the CF Registry of Ireland.

Application Procedure:

To apply for CFRI data you will need to complete and sign an electronic version of the CFRI data application form and send it to info@cfri.ie. A listing of CFRI variables is available upon request. Any association with private companies, in particular associations with pharmaceutical companies, should be disclosed in the application.

All applications will be reviewed by the CFRI Scientific Committee, who will decide if the data request will be approved or not, based on the following criteria: merit, validity, relevance, feasibility and quality. This decision will be final. No data should be used for marketing purposes.

It is the responsibility of the applicant to obtain appropriate ethics committee approval for any research relating to the data supplied, and to submit this approval with the application.

Once the application has been approved, and the applicant wishes to expand on the scope of work of project or would like to perform related analysis that require additional data, the additional request should be sent to info@cfri.ie.

It is advisable that templates of summary data table are provided by the applicant. Alternatively, the CFRI statistician will create tables in a format considered appropriate.

Please note that only anonymised data will be provided and sent in an encrypted file to the data applicant. This will be aggregated data. In exceptional cases, when the research objective is of interest to the CFRI and at the CFRI's discretion, anonymised raw data may be released.

If the research aim is of interest to the CFRI and approved by the Scientific Committee, potential collaboration with the CFRI can be discussed, including statistical analysis.

Use of Data:

In the event that the application is approved, the applicant agrees to use the CFRI data in accordance with the terms and conditions of the following agreement:

1. Data shall be obtained and used only for the purpose(s) specified by the applicant, and shall not be processed in any manner incompatible with that purpose(s).
2. Data requested shall be adequate, relevant and not excessive in relation to the purpose for which they are processed.
3. Data processed for any purpose(s) shall not be kept for longer than necessary for that purpose(s). Upon the completion of data analyses, you must destroy the original and any duplicate data files and notify the CFRI of the same.
4. The data applicant ensures that the data are stored in a secure manner and (s)he abides by the requirements to ensure confidentiality of the data. Data must be kept secure from any potential abuse.

5. Appropriate technical and organisational measures must be taken against unauthorised or unlawful data processing and against accidental data loss, destruction, or damage.
6. Data transfer onto a portable device such as a laptop, USB stick, CD or disk must ensure that the data is encrypted, so that data remain safe, even if the portable device is lost or stolen.
7. The data applicant ensures that data shall not be transmitted to another party or legal or natural person without the CFRI's permission.
8. The data applicant is liable for any damage-causing events (e.g. loss of data), transfer to other persons/parties/ companies etc.
9. The CFRI reserves the right – without prior notification – to retract its permission for data use. Additionally, the CFRI reserves the right to take legal action against the data applicant for compensation in case of inappropriate use of data or in case of a data procession in any manner incompatible with the purpose(s), including their right to penal actions.

Publication Policy:

Approved data applications should lead to the publication of CFRI data in a peer-reviewed journal(s). Submission to a peer-reviewed journal should be aimed for within 2-3 years upon receipt of the data. If this is not possible, the approved data application should result in the publication of an abstract.

The CFRI should be acknowledged for the release and use of the data in any oral presentation, publication etc., of the data, with the text: *"We would like to thank the Cystic Fibrosis Registry of Ireland for providing access to patient data, the individual CF centres for allowing the use of data, the parents/guardians of children, and adults with CF participating in the registry."*

Where CFRI provide statistical services, the contribution of the CFRI statistician should be reflected in manuscript authorship listings, as per journal manuscript authorship criteria.

Prior to submission of manuscripts, abstracts or posters, a final draft should be sent to info@cfri.ie for review by the Scientific Committee. A review period of 20 days is required for manuscripts, and 10 working days for abstracts/posters. This is to ensure verification that the interpretation and conclusions of the authors are accurate and consistent with the scientific objectives initially stated in the proposal.

A copy and/or link of any publication (also report, abstract, article, programme, essay, dissertation etc.) resulting from use of CFRI data must be forwarded to the info@cfri.ie, on notice of the acceptance by the journal or scientific organization, together with the details of the publication.

Should any intellectual property rights arise from the use of the data, the CFRI should be informed. The applicant and CFRI will be required to enter into separate agreement on patents, copyright, disclosure and sharing of financial returns.

The study title and institution name of approved data applications may be listed on the CFRI website.

Timelines and Costs:

All applications will undergo a two-week review, and producing the requested data-set will take a further 15-20 working days (minimum). The CFRI charges a fee for the handling of the application (whether the application is approved or not), extraction and analysis. To promote and stimulate research in CF, the handling and data extraction fee will be waived for academic researchers, research groups and patient organisations.



The Cystic Fibrosis Registry of Ireland

Where data analysis is required, a fee will be charged. The applicant will receive a cost-estimate based on the hours necessary. Once the cost-estimate is approved and signed, the CFRI will provide the data-set and send an invoice of the actual hours spent on the analysis.

CF Registry of Ireland Data Application Form

All requests for data extraction/analysis for information held by the Cystic Fibrosis Registry of Ireland (CFRI) must be submitted on this form. We advise you to read all information and complete the form as best as possible to ensure review of your application.

You can email the completed form to gletcher@cfri.ie

Applicant Details

Primary Investigator/Applicant:			
Co-Investigator(s):			
Institution/Organisation:			
Title of Study/Protocol:			
Position:			
Address:			
Email:		Phone:	
		Fax:	
Date of request:			

Disclosure

Please disclose any associations with private companies, especially pharmaceutical companies:

Research Project Information

Project Name:	
Project Objective(s):	
Project Description:	

Background Information (e.g. Clinical Relevance):	
Research Question/ Hypothesis:	
Study Design:	
Cohort Definition:	
Method of Analysis:	
Start and End Date:	
Purpose for which the data is required/potential use of the data:	Research <input type="checkbox"/> Audit <input type="checkbox"/> Clinical Trial <input type="checkbox"/> Other <input type="checkbox"/> please specify _____
Type of Data Required:	Raw Data <input type="checkbox"/> Summary Tables or Graphs <input type="checkbox"/>
Ethical Approval From University/Hospital:	Yes <input type="checkbox"/> No <input type="checkbox"/> Application in progress <input type="checkbox"/> Not applicable <input type="checkbox"/>
Data Requirements	
Follow-up years:	
Information required: (age, gender, etc. Please provide table templates if possible)	
Statistical services:	Statistical analysis to be conducted by CFRI? Yes* <input type="checkbox"/> No <input type="checkbox"/> <small>*Charges are applicable if statistical analysis is undertaken by CFRI</small>
Date required:	

Read and Agree:

I have read and agree to abide by the terms described in this Data Application Form from the Cystic Fibrosis Registry of Ireland.

Primary Investigator/Applicant Name (print):

Head of Department/Institution Name (print):

Primary Investigator/Applicant Signature:

Head of Department/Institution Signature:

Date: _____

Date: _____