UK Cystic Fibrosis Registry

Data sharing policy

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Introduction

The UK Cystic Fibrosis Registry

The UK Cystic Fibrosis Registry is a Research Ethics Committee approved research database holding demographic, clinical care, and health outcome data on consenting people with cystic fibrosis (CF).

Data are entered onto a secure web based platform by clinical care teams in all specialist CF centres across the UK. More information, including Annual Data Reports, can be found at www.cysticfibrosis.org.uk/registry.

Governance

Sponsor

The UK CF Registry is sponsored by the Cystic Fibrosis Trust, and the Chief Investigator for the study is Dr Siobhán Carr, Paediatric Respiratory Consultant at the Royal Brompton Hospital.

Management team

The UK CF Registry Management Team are employed by the Cystic Fibrosis Trust:

- UK CF Registry Lead
- UK CF Registry Data Manager
- UK CF Registry Development Manager
- UK CF Registry Administrator

Statistical support

Statistical support is provided by the Cystic Fibrosis Trust.

Registry Steering Committee

The Registry Steering Committee Terms of Reference are available on the Cystic Fibrosis Trust website. Its role is to provide strategic direction for the Registry development, in consultation with the CF community.

Registry Research Committee

The Registry Research Committee is a sub-committee of the Registry Steering Committee. It is responsible for receiving, reviewing and deciding upon requests for access to Registry data, ensuring that data are used to their maximum potential whilst safeguarding the identity of individuals.

Purpose

This policy is designed to ensure fair, transparent and ethical access to UK CF Registry (UKCFR) for high quality research, service evaluation and audit use for the purpose of improving care, quality of life and clinical outcomes of people with CF. Registry data requests are only granted if in-line with the Research Ethics Approval (REC ref: 07/Q0104/2) for the UK CF Registry, including the Consent provided by people with CF, and relevant Data Protection Legislation, including the Data Protection Act 1998.

Scope

- This policy applies to both internal (Cystic Fibrosis Trust and Steering/Research Committee members) and external applications for access to data or analysis of the UKCFR
- The policy applies to service specific (where the applicant is not employed by that service), multi-centre and national data requests
- The policy is applicable to data requests pertaining to audit, service evaluation and research
- This policy **does not** apply where a CF service needs access only to its own Registry data
- This policy **does not** apply to Registry-based study modules or post marketing surveillance, which are approved by the Registry Steering Committee through a separate process

Policy

Submitting a request

All requests must be submitted using the Registry Data Request application form available for download from www.cysticfibrosis.org.uk/registry, and emailed to registry@cysticfibrosis.org.uk. A list of current requests is available on these pages. They must include a plain English summary of the project for publication on the Cystic Fibrosis Trust website.

A member of the UK CF Registry team will acknowledge receipt of the request.

Quality control

The Chair of the Research Committee and the Chief Investigator will screen the request for missing or unclear information prior to it going out to the Registry Research Committee for evaluation. This includes whether the following information is present:

- The requestor has provided details of specific data items required and why
- The requestor has specified the cohort required and why
- The requestor has specified the data range required and why
- Whether the project has been granted funding support, and if so, where from
- The entire research team is listed including their role and institution, and comprises of a clinician with experience in cystic fibrosis, and a statistician

Evaluation

The Registry Research Committee **does not** perform a peer review function; it is anticipated that this will be performed by the editorial/scientific committee involved in reviewing conference and journal submissions, prior to the publication of any research. It is expected that researchers will register individual Registry-research projects with their local Research and Development departments.

The committee does not evaluate the scientific validity of the research question, or dictate the research question, research team, collaborators, or analysis methodology. The Research Committee may make suggestions regarding the above, based on members' expertise and experience, but these are not binding and will not affect the approval of the request.

The Registry Research Committee, including co-opted clinical members of the Registry Steering Committee will evaluate the suitability of Registry Data Requests using the following criteria:

Are the Research team appropriately configured to comply with information governance standards?	Y/N/ More info needed
The request is in-line with the Guidelines for data release	Y/N
Does the research team include CF clinical and statistical expertise?	Y/N
Are there obvious issues with the suggested methodological approach (e.g. the data required do not exist, or demonstrates a clear lack of understanding of the data or clinical background. The default position is to grant data where data is exploring clinical questions with a competent team even if the rationale is not compelling to the panel since this is an issue of peer review)?	Y/N/ More info needed
Reviewer comments:	

Summary and Chair decision

The Registry Data Manager will provide a summary of all evaluation feedback to the Chair of the Registry Research Committee and the UK CF Registry Chief Investigator for a final decision to be made.

The Chairs will agree a written response, and the Registry Data Manager will provide this, along with each individual committee member response, back to the Evaluation group. Group members have five working days to raise queries or concerns about the final decision before the Chairs' decision is passed on to the Requestor. The Registry Data Manager will reported back to the Registry Research Committee as part of the Data Request Overview standing agenda item at quarterly meetings of the Research Committee. The Registry Data Manager will also inform requestors if similar work is already being undertaken as part of another Registry data request. The requestor may wish to contact the lead for the ongoing request, but there is no obligation for them to do so.

Turnaround time

The Registry team will endeavour to provide the requestor with a decision from the Registry Research Committee within six weeks of receipt of the request. Data will be provided eight weeks after the original request as a minimum. The resources of the Registry team are finite, and requestors should plan ahead to allow the maximum possible time for processing data requests.

Data sharing agreement

Once approval has been given, the requester(s) and the senior investigator for the project will be asked to sign a data sharing agreement. Data will not be extracted until a signed copy of this agreement has been returned to the Registry Data Manager.

Guidelines for data release

Only the minimum data will be provided. The minimum data, justified by the requestor, will be provided. From least to most:

1. Aggregated, anonymised
2. Patient level, anonymised (no patient identifiers* included)
3. Patient level, pseudonymised (CFTID only included)

*Patient identifiers include:

- First name
- Middle name
- Surname
- NHS number
- CHI number
- Full date of birth
- Full date of death
- Full post code

Regarding date of birth and death, the committee will, where possible, provide the age at annual review/encounter in years and whole months. Where date of birth is required, MM/YYYY, with the day set to the 15th of the month will be provided.

If a researcher needs the exact date of birth or death in order to perform their analysis, this must be clearly and explicitly stated with a rationale provided for the committee's consideration. Should full date of birth be provided, it may be necessary for the committee to put in place additional safeguards to ensure that the risk of re-identification is minimised.

Individual full postcodes will not be given out. For research requiring location for analysis such as deprivation scores, where possible already derived postcode related deprivations scores will be provided. Alternatively an anonymous linkage process can be arranged by the UK CF Registry team.

Small numbers

The UK CF Registry complies with Office of National Statistics guidance on small denominators. Where a denominator is less than five the actual number is to be supressed ('<5'). This policy should be heeded by requestors when publishing information derived from a Registry Data Request.

Study feasibility requests

Requests intended to evaluate the number of people with cystic fibrosis potentially eligible to participate in a clinical study fall under this category. No centre level information is provided to the requestor in this case, with the Registry team acting as facilitators.

- Requestor provided with the total number of eligible candidates, broken down by devolved nation treatment centres where required

- Treating centres provided with a list of Registry IDs for potentially eligible patients, as well as information about the study and contact details of the PI
    - Onus is on the clinical team in each respective centre to contact the study team or discuss the study with their patients if they feel appropriate.

Steering Committee requests

Where a member of the Steering Committee, Research Committee, or Cystic Fibrosis Trust is a member of the Research team, they must be declared as a collaborator on the Data Request form. The Registry Data Manager will not include the member(s) in the evaluation process, and the final decision will be communicated as per the usual process for external requesters.

Chair's action

The Chief Investigator and the Chair of the Research Committee may take Chair's action where a request is for aggregated data, a resubmission as a result of feedback from the Research Committee that now clearly meets the requirements, or is an amendment to a request previously approved by the RRC. The decision will be documented by the Registry Data Manager and reported back to the Registry Research Committee as part of the Data Request Overview standing agenda item at quarterly meetings of the Committee.

Where the Chief Investigator or Chair are a member of the requesting research team, Chair's action will be taken by the role not involved in the Request and verified by the UK CF Registry Lead.

Project completion

Upon project completion data requesters will provide details of their project outputs and either electronically shred their data, or provide it to the Cystic Fibrosis Trust Registry team for archiving along with analysis syntax if this is offered by research team (e.g. Stata analysis code).

Data will be provided from a verified dataset available after the annual report for the given year is published.

Data extraction fees

Whilst the UK CF Registry does not charge for data, it must recoup costs of data handling (including extract and cleaning), project management, and analysis (where applicable) on behalf of third parties. The charging structure outlined below is designed to be fair, proportionate, and transparent whilst furthering the Registry's aim of stimulating research use of the data for the benefit of people with cystic fibrosis.

The Registry supports high quality research conducted by appropriately configured groups. These will usually include clinical, academic and statistical expertise as a minimum. As such, there is an expectation that non-commercial research use of UKCFR data will be grant funded, and that such a grant will incorporate the costs laid out herein.

Description	Cost
Extract from locked, validated dataset	£5,000
Database search for study feasibility request	£2,200
Extract update or amendment to existing request	£250
Acting as a Trusted Third Party (TTP)	£500p/d
Analysis work	£500p/d

Exemptions

Participating NHS Trusts

Applications made by employees of NHS Trusts that have met the Registry's criteria for case ascertainment and data completeness are exempt from the charges associated with data handling and project management. This is on the condition that the CF clinic director sponsors or is directly involved in the project. Charges for analysis or linkage of Registry data on behalf of participating Trusts may be subject to a charge, depending upon its complexity at the discretion of the Research group but in-line with the charging principles set out above.

Clinical Reference Group (CRG): A01. Specialised Respiratory

The Registry acknowledges that evidence-based decision making of the CRG will benefit people with CF. As a result top-line analysis may be exempt from charge, depending upon its complexity at the discretion of the Research Committee, but in-line with the charging principles set out below. This exemption does not cover the provision of patient level data, or any patient level or aggregated analysis of machine readable data that will be utilised by a third party or sub-contractor.

Contractual deliverables

Data exporting and analysis listed as deliverables as part of in-force contracts are not bound by the charging structure detailed below. Variations to or additional data/analysis requested is subject to charge.

Non funded academic research

This exemption applies only to groups not already covered in the exemptions laid out above. The Research group may waive a fee where grant funding is not available for the research project proposed. This waiver is dependent upon:

- The principal investigator or sponsor holding a current academic appointment
- A rationale being accepted by the Registry Research Committee for why a grant application was rejected or not submitted
- The complexity of the request's data/analysis

Joint datasets

The UK CF Registry seeks to establish collaborative relationships within the cystic fibrosis Registry network worldwide; principally by merging pseudonymised/anonymised datasets in order to make meaningful comparisons between countries. Proposals for new joint datasets will be considered by the Registry Research Committee.

European Cystic Fibrosis Patient Registry (ECFSPR)

The European Cystic Fibrosis Patient Registry is a Europe-wide Registry of anonymised, core data on people with cystic fibrosis. Whilst some countries submit data directly into the ECFSPR, those with existing National Registries submit an anonymised export on an annual basis. Those submitting data are automatically part of the ECFSPR Steering Committee, which is consulted on every data request. Countries have the right to opt out of their data being provided as part of any data request, and can request that applicants approach them directly.

US/UK comparisons

The UK CF Registry and CFF Patient Registry have a long-standing collaboration that has produced a cross sectional comparison between the two countries using a comprehensive comparison methodology[1]. A longitudinal analysis is now ongoing.

Industry requests

Industry will only be provided with aggregated data. Requestors must declare when their request originates from or is sponsored by Industry. Whilst requests to further the development, availability, or evaluation of new therapies for people with cystic fibrosis will be considered, those relating to marketing or promotion of products will not be granted.