Application for data from the European Cystic Fibrosis Society Patient Registry (ECFSPR)

Introduction:

The European Cystic Fibrosis Society Patient Registry (ECFSPR) collects anonymised demographic and clinical data from consenting cystic fibrosis (CF) patients in Europe. The data are collected according to agreed inclusion criteria, definitions and coding. For a detailed list of variables, their definition and the inclusion criteria we refer you to the website www.ecfs.eu/projects/ecfs-patient-registry/Variables-Definitions. With information on more than 44,000 patients and longitudinal data from 2008 to 2016, the ECFSPR database reflects the reality of CF across Europe and is a unique basis for large-scale epidemiological and prognostic analyses.

To apply for ECFSPR data you will need to complete the application form and sent it with the Use of Data form to the ECFSPR Executive Coordinator, ecfs-pr@uzleuven.be. Any association with private companies, in particular associations with pharmaceutical companies, should be disclosed in the application.

Please read this document carefully.

Procedure:

All applications will be reviewed by the ECFSPR Scientific Committee. Applications from Industry will also be reviewed by the ECFS Clinical Trials Network (CTN). Based on the recommendation of the Scientific Committee, the ECFSPR Steering Group (composed of national representatives of the countries that contribute data to the ECFSPR) will decide if the data request will be approved or not. This decision will be final. For further information on the procedure we refer to the ECFSPR Code of Conduct www.ecfs.eu/files/Code_Of_Conduct.pdf.

As the ECFSPR is subject to the standard terms of the Danish and European Data Protection legislation any applications from a non-European country must ensure an adequate level of protection (EU Directive 95/46/EC chapter IV, article 25.1), and must be approved by the Danish Data Protection agency before release of data.

For data applications that request country specific data, the ECFSPR will ask the country coordinators whether they are in favour of providing the data via their own registry or agree for the ECFSPR to provide the data.

Applicants will be asked to sign an agreement on the Use of Data, in which they declare that the data will be used for the sole purpose indicated in the application and shall not be kept for longer than necessary for that purpose(s). The Use of Data Statement needs to be sent together with the Data Application Form.

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 the Executive Coordinator, ecfs-pr@uzleuven.be.

If other researchers apply for data to pursue similar analyses, they may be granted access too based on the outcome of the review process. Additionally, the ECFSPR will liaise with the research groups, upon agreement of both parties, to explore potential collaboration to get the best possible result for the CF community.

The ECFSPR statistician will create tables of required information. In case of a complex analysis a more detailed discussion by email or phone might be required to decide how to proceed. We advise applicant to send us mock tables to ensure that the data is provided in the desired format. Alternatively, we will create tables in the format we consider appropriate.

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

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

Publication policy:

- All approved scientific projects should be published in peer-reviewed journals. If this is not possible, the approved project should be published as an abstract for a conference, preferably the annual ECFS conference.
- Completion of the manuscript for submission to peer-reviewed journals should be aimed for within 2-3 years upon receipt of the data.
- The ECFSPR should be acknowledged in any oral presentation/release of the data and any publication with the text:

  "*We would like to thank the European Cystic Fibrosis Society Patient Registry for providing access to patient data and thank the individual country representatives for allowing the use of data, www.ecfs.eu/projects/ecfs-patient-registry/steering-committee).*"
- Prior to submission of manuscripts, abstract or posters a copy should be sent to the ECFSPR Executive Coordinator, ecfs-pr@uzleuven.be, for review by the Scientific Committee. We request 20 working days for manuscripts, and 10 working days for abstracts/posters.
- A copy of any publication must be forwarded to the ECFSPR Executive Coordinator, ecfs-pr@uzleuven.be, on notice of the acceptance by the journal or scientific organisation together with the name of the publication and/or definition of the scientific organisation (name, place and date).
- Scientific projects will be published on the webpage of the ECFSPR as a link to the publication. Non-scientific projects will be published with subject and aim on the ECFSPR webpage.
- The national coordinators and centre directors will be informed of the publication by the ECFSPR.

Time lines and Costs:

All applications will be handled as received. Please take into account that the process of review of the request and producing the requested data-set will take a minimum of 15-20 working days.

The ECFSPR charges a fee for the handling of the application, whether the application is approved or not. To promote and stimulate research in CF, the handling fee will be waived for researchers/research groups and patient organisations.

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

Patient organisations: free of charge.

Academic researchers who are ECFS members: free of charge.

Independent researchers/research groups:

Handling:	Free of charge;
Data-extraction:	Free of charge;
Data-analysis[3]:	€ 250.00 per hour (equal to the number of hours spent on the analyses).

Industry:

Handling[1]:	€ 2.500.00; If the initial application needs to be amended and resubmitted an additional € 250,00 will be charged;
Feasibility[2] & data-extraction[3]:	€ 25,000.00;
Data analysis[4]:	€ 250.00 per hour (equal to the number of hours spent on the analyses);
Overhead :	50% of the hours for data–analysis.

1 **Handling: the act or process of processing the data-application internally to the different committees for review and approval.**

2 **Feasibility: the act or process of checking the availability of the required data.**

3 **Data-extraction: the act or process of retrieving data out of the database.**

4 **Data-analysis: the process of inspecting, cleaning, transforming and modelling the data (with the goal to highlight useful information, suggest conclusions and support decision-making).**

APPLICATION FORM
ECFSPR DATA

All requests for data extractions/data analysis from the European Cystic Fibrosis Society Patient Registry (ECFSPR) must be submitted with 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 ecfs-pr@uzleuven.be.

Applicant details

Name Primary Investigator (incl. title):			
Primary contact (if not PI):			
Institution/Organisation:			
Position:			
Address:			
Email:		Phone:	
Date of request:			

Disclosure

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

Research Project Information

Project Name:	
Project Objective(s):	
Description of the Project:	
Brief Background Information (incl. justification of the 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 (incl. anticipated publications, reports, presentations, analyses etc.):				
Ethical Approval University/Hospital:	☐ Yes	☐ No	☐ In pipeline	☐ Not applicable
Data Requirements				
Follow-up years (data are available from 2008 to 2014):				
Information required (for example age, gender, etc. - see the list of variables in attachment):				
	Please provide mock tables if possible: ☐ yes, attached ☐ no* Statistical collaboration with ECFSPR: ☐ yes ☐ no *The ECFSPR will provide tables as they think is best, no edits will be possible.			
Deadline:				

Statement on the use of data from the European Cystic Fibrosis Society Patient Registry (ECFSPR)

The applicant agrees to use the ECFSPR data in accordance with the terms and conditions of the following agreement.

For the purposes of these terms and conditions of this agreement:
"Data applicant" or "applicant" shall refer to the person who submits an application to the ECFSPR Scientific Committee in order to obtain data extracts from the ECFSPR for research.
"Application form" shall refer to the form that the data applicant has to fill out and submit to the ECFSPR Executive Coordinator for ECFSPR data.

Use of Data:
Data shall be obtained and used only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.

Data extract/data analysis of the ECFSPR is obtained originally for the purpose provided in the application form by the applicant who ensures that these data will BE EXCLUSIVELY USED FOR that/those purpose(s) stated in the application form and not for any other purposes.

Data shall be adequate, relevant and not excessive in relation to the purpose for which they are processed.
Data processed for any purpose(s) shall not be kept for longer than necessary for that purpose or purposes.
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.

Appropriate technical and organisational measures must be taken against unauthorised or unlawful data processing and against accidental data loss, destruction, or damage.

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.

The data applicant ensures that data shall not be transmitted to another party or legal or natural person without the ECFSPR's permission.

Part or all of these data may be freely copied and incorporated unaltered into a research publication or a relevant publication on the Internet, only for research purposes and not for commercial gain, and only for the purposes mentioned in the application form, subject to the source (ECFSPR) being appropriately acknowledged.

The data applicant is liable for any damage-causing events (e.g. loss of data), transfer to other persons/parties/ companies etc. The ECFSPR reserves the right – without prior notification – to retract its permission for data use. Additionally, the ECFSPR 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:

All approved scientific projects should be published in peer-reviewed journals. If this is not possible, the approved project should be published as an abstract for a conference, preferably the annual ECFS conference.

Completion of the manuscript for submission to peer-reviewed journals should be aimed for within 2-3 years upon receival of the data.

The ECFSPR should be acknowledged in any publication with the text:
"We would like to thank the European Cystic Fibrosis Society Patient Registry for providing access to patient data and thank the individual country representatives for allowing the use of data, www.ecfs.eu/projects/ecfs-patient-registry/steering-committee)."

Prior to submission of manuscripts, abstract or posters a copy should be sent to the ECFSPR Executive Coordinator, ecfs-pr@uzleuven.be, for review by the Scientific Committee. We request 20 working days for manuscripts, and 10 working days for abstracts/posters.

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Scientific projects will be published on the webpage of the ECFSPR as a link to the publication. Non-scientific projects will be published with subject and aim on the ECFSPR webpage.

The national coordinators and centre directors will be informed of the publication by the ECFSPR.

The present Terms of Use shall be governed by the Danish law. Venue for any dispute shall be Denmark.

Date: _____

Printed name: _____ Signature: _____