## 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. With information on more than 54,000 patients and longitudinal data from 2008 to 2023, the ECFSPR database reflects the reality of CF across Europe and is a unique basis for large-scale epidemiological and prognostic analyses.

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 ECFSPR website: <https://www.ecfs.eu/projects/ecfs-patient-registry/Variables-Definitions>.

To apply for ECFSPR data you need to complete the Data Application Form and send it, together with the Use of Data Form, to [coordination@ecfregistry.eu](mailto:coordination@ecfregistry.eu).

N.B. Any association with private companies, particularly associations with pharmaceutical companies, must be disclosed in the application.

**Please read everything carefully before starting to complete the form.**

**Procedure**

* To apply for ECFSPR data you need to complete the **Data Application Form** and send it, together with the **Use of Data Form**, to [coordination@ecfregistry.eu](file:///C:\Users\servi\Documents\Work\HandoverRelatedTasks\coordination@ecfregistry.eu).
* All applications are reviewed by the ECFSPR Scientific Committee.
* Applications from Industry are also reviewed by the ECFS Clinical Trials Network (CTN).
* Based on the recommendation of the Scientific Committee, **the ECFSPR Steering Group** (the national representatives of the countries that contribute data to the ECFSPR) **decides if the data request is to be approved or not.** This decision is final. For further information on the procedure, we refer you to the ECFSPR Code of Conduct [www.ecfs.eu/sites/default/files/general-content-files/working-groups/ecfs-patient-registry/ECFSPR\_CodeofConduct\_1.1.pdf](http://www.ecfs.eu/sites/default/files/general-content-files/working-groups/ecfs-patient-registry/ECFSPR_CodeofConduct_1.1.pdf).
* The ECFSPR is subject to the standard terms of the Danish and European Data Protection legislation and 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 asks 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 are 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 Form 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 analyses that require additional data, the additional request should be clearly referenced and sent to [coordination@ecfregistry.eu](mailto:coordination@ecfregistry.eu)**.**
* If other researchers apply for data to pursue similar analyses, they may also be granted access, 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. Where complex analyses are required, a more detailed discussion by email or phone may be required to decide how to proceed. **We advise applicants 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 at 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 thank the people with CF, and their families, for consenting to their data being included in the European CF Society Patient Registry (ECFSPR). We thank the centres and individual country representatives for allowing the use of the data, and the ECFSPR for providing access to anonymised patient data*”.

* For applications from researchers and patient organisations, the recommendations of the International Committee of Medical Journal Editors (ICMJE) apply to the authorship rights. The ECFSPR, i.e. the participating national representatives, members of the Scientific Committee and the statisticians, should be acknowledged in the publication as a list of contributors/collaborators, including the names, emails and affiliations. If the paper is Pubmed listed, the group members will come up as “Collaborators”, but do not appear in the author list. For an updated list please contact [coordination@ecfregistry.eu](file:///C:\Users\servi\Documents\Work\HandoverRelatedTasks\coordination@ecfregistry.eu).
* Prior to submission of manuscripts, abstract or posters, a copy should be sent to [coordination@ecfregistry.eu](file:///C:\Users\servi\Documents\Work\HandoverRelatedTasks\coordination@ecfregistry.eu) for review by the ECFSPR Scientific Committee. To review and reply to the applicant we require 20 working days for manuscripts, and 10 working days for abstracts/posters.
* A copy of any publication must be forwarded to [coordination@ecfregistry.eu](file:///C:\Users\servi\Documents\Work\HandoverRelatedTasks\coordination@ecfregistry.eu) 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.

**Timeline**

* 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 and may be longer, depending on the number of applications currently under review and the type of request.

**Costs**

* 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.
* The income received will be used to support the data-handling, review, extraction and report services.

**Patient organisations:** free of charge.

**Academic researchers who are ECFS members:** free of charge.

**Independent researchers / research groups:**

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| H Handling1: | f free of charge; |
| D Data-extraction3: | F free of charge; |
| D Data-analysis4: | € 250.00 per hour (for the number of hours spent on the analyses). |
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**Industry:**

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| --- | --- |
| Handling1: | € 5,000.00;  If the initial application needs to be amended and resubmitted, an additional € 250,00 will be charged; |
| Feasibility2 & data-extraction3:  Data analysis4: | Min. € 25,000.00, to be decided on a case by case basis;  € 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.

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| **Data Application Form**  **ECFSPR DATA** | | | |
| All requests for data extraction/data analyses from the European Cystic Fibrosis Society Patient Registry (ECFSPR) must be submitted using this form. We advise you to read all information and complete the form as best as possible to ensure review of your application.  Send the completed **Data Application Form**, together with the **Use of Data Form**, to:  [coordination@ecfregistry.eu](mailto:coordination@ecfregistry.eu) | | | |
| **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, particularly 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: |  | | |

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| --- | --- | --- | --- | --- |
| **Research Project Information (cont.)** | | | | |
| 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 2020): |  | | | |
| 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: |  | | | |

## Use of Data Form

## (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, and must be destroyed when the purpose has been met. In case the purpose hasn’t been met, for whatever reason, the data must be destroyed after a period of 3 years.
* 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.
* The European General Data Protection Regulation legislation, applicable to the European countries, will be respected by the countries outside of Europe.

**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 oral presentation/release of the data and any publication with the text:

“*We thank the people with CF, and their families, for consenting to their data being included in the European CF Society Patient Registry (ECFSPR). We thank the centres and individual country representatives for allowing the use of the data, and the ECFSPR for providing access to anonymised patient data*”.

* For all data-applications, the recommendations of the International Committee of Medical Journal Editors (ICMJE) will apply to the authorship rights. The ECFSPR, i.e. the participating national representatives, members of the Scientific Committee and the statisticians, should be acknowledged in the publication as a list of contributors/ collaborators, including the names, emails and affiliations. If the paper is *Pubmed* listed, the group members will come up as “Collaborators”, but do not appear in the author list. For an updated list please contact [coordination@ecfregistry.eu](mailto:coordination@ecfregistry.eu).
* For data-applications from Industry, a co-authorship group will be established between ECFSPR and the Company beforehand, and depends on the contribution of each party. The ECFSPR will determine the members of the ECFSPR authorship group, who should revise the manuscript critically for important intellectual content and ensure accuracy and integrity of the data for the manuscript. If Industry is not interested in a publication, or when twelve (12) months have passed following receipt of the ECFSPR results of the data request – whichever is first – ECFSPR is free to publish on their own as appropriate. Industry recognizes the fundamental interest of ECFSPR in scientific publication; in particular the performance of theses and promotion procedure will not be hindered. Publications are made in accordance with the normal standards of scientific authorship.
* Prior to submission of a manuscripts, abstract or posters a copy should be reviewed by the Scientific Committee. The copy is to be sent to [coordination@ecfregistry.eu](mailto:coordination@ecfregistry.eu). We request at least 30 working days (6 weeks) before submission for publication for manuscripts, and 15 working days for abstracts/posters.
* A copy of any publication must also be forwarded to [coordination@ecfregistry.eu](mailto:coordination@ecfregistry.eu) 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.
* The present Terms of Use shall be governed by the Danish law and the European General Data Protection Regulation. Venue for any dispute shall be Denmark.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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