ECFS Patient Registry (ECFSPR)
– Terms of Reference –

1. Aim

The aim of the European Cystic Fibrosis Society Patient Registry (ECFSPR) is to gather data that is accurate (measured against an internationally agreed standard) and which can be used for patient benefit as defined in the patient consent.

In reaching this aim, the ECFSPR is:

- To measure, and compare epidemiological and clinical aspects of cystic fibrosis (CF) in the participating countries, thereby encouraging the identification of new standards of CF management;
- To provide data for epidemiological research and identify groups of patients potentially eligible for multi-centre trials.

2. Deliverables

A. Data that is of sufficient quality to permit epidemiological research;

B. Annual epidemiological reports to be submitted to the ECFS:

- The annual epidemiological reports will be maintained at the ECFS office and will be published on both the ECFS and ECFSPR webpages;
- The annual epidemiological report will include epidemiological presentation of core data;
- Tables and graphs will show data aggregated on a European level and on individual country level. Data aggregated on individual centre level will be accessible only to the centre's director and to a national registry steering committee in the event that such a recognized organisation exists for the country.

3. Governance

Contributors group:

The ECFSPR Contributors Group is defined as anyone who contributes data to the ECFSPR.

Steering Group:

The ECFSPR Steering Group will set the strategic direction and areas of priority of the ECFSPR.

Responsibilities of the Steering Group:

a. Ensures the project is aligned with the general ECFS strategy;
b. Approves formal collaborations of ECFSPR with external organisations;
c. Recommends individuals to serve on the Executive Committee to replace members rotating off. Such recommendations are subject to the approval of the ECFS Board;
d. Nominates the ECFSPR Director by a voting process. The nomination is subject to approval by the ECFS Board;
e. Ensures the project makes good use of assets;
f. Assists with resolving strategic level issues and risks;
g. Provides advice and guidance on business issues facing the project;

h. Uses influence and authority to assist the project in achieving its outcomes;
i. Reviews and approves final project deliverables.

The ECFSPR Steering Group will meet twice a year, in conjunction with the European CF Conference in June and in January at the combined ECFSPR and ECFS-CTN meeting.

The ECFSPR Steering Group may create committees amongst its members to focus on specific aspects of the Registry.

The ECFSPR Steering Group is composed as follows:

Voting members:

- ECFSPR Director, chairperson;
- 1 national representative per country contributing to the ECFSPR (an individual Country Manager or a representative of the National Registry, or an elected individual representing centres from a country);
- 2 members appointed by Cystic Fibrosis Europe, the European Federation of Patients organisations.

The Steering Group will be augmented by the following non-voting members:

- a statistical expert;
- a data protection legal and ethics expert on an ad-hoc basis;
- representatives from Non-European CF Patient Registries;
- a representative from the ECFS Clinical Trials Network;
- ECFSPR Executive Coordinator;
- a “Trusted third party” (responsible for centre codes for anonymisation purposes).

The ECFSPR Steering Group will be chaired by the Director.

The responsibilities of the ECFSPR Director are:

- Sets the agenda for each meeting;
- Ensures that agendas and supporting materials are delivered to members in advance of meetings;
- Makes the purpose of each meeting clear to members and explains the agenda at the beginning of each meeting;
- Clarifies and summarizes what is happening throughout each meeting;
- Encourages broad participation from members in discussion by calling on different people;
- Ends each meeting with a summary of decisions and assignments;
- Follows-up with absent members;
- Reports to the ECFS Board and Annual General Meeting (AGM).

The ECFSPR Director is appointed by the ECFS Board, based on a nomination from the ECFSPR Steering Group. The tenure will be of 3 years. In case of non-compliance with the ECFS Strategy, the ECFS Board has the right to dismiss the Director with a four weeks’ notice. In the last year of tenure, the Director will train the new Director to the position. The ECFSPR Director is a co-opted member of the ECFS Board.

Executive Committee:

Responsibilities of the Executive Committee:

- Implements the strategy and policies decided by the ECFS Board;
- Implements the ECFS Board's overall recommendations for change;
- Proposes new strategy and policies to the Steering Group;
- Monitors the ECFSPR activities, the operation, and all activities where ECFSPR undertakes legal obligations;
- Reviews reports and budgets prepared by the ECFSPR Executive Coordinator and makes recommendations to the Steering Group;
- Prepares an annual strategic and financial report to be submitted to the ECFSPR Steering Group and subsequently to the ECFS Board for approval.

The Executive Committee is comprised of:

- ECFSPR Director;
- 3 Members of the ECFSPR Steering Group;
- one representative of the patient associations nominated by CF Europe.

Ex Officio members (non-voting):

- ECFS Executive Director;
- ECFSPR Executive Coordinator;
- one statistical expert;
- one CTN representative;
- one ECFSPR Liaison Officer to the European Platform for Rare Disease Registries (EPIRARE) and other EU initiatives for rare diseases;
- an external legal expert will be augmenting the Executive Committee as consultant on an ad-hoc basis.

Members of the Executive Committee will be appointed for 3 years and on a rotational basis. In order to implement the rotation system, the members of the first Executive Committee will be appointed for either 2 years or 3 years. No Executive Committee member can stand for election for more than two consecutive terms of office.

The Executive Committee is accountable to the ECFS board.

The Executive Committee will hold teleconferences twice a month and the minutes will be circulated to the entire ECFSPR Steering Group.

The ECFSPR Executive Coordinator provides a central role for information exchange, project coordination, management of sensitive timelines and general administration.

Scientific Committee

All applications for data extracts from the ECFSPR will be reviewed and assessed by the Scientific Committee. Application Forms requesting data extracts are to be sent via email to the ECFSPR Executive Coordinator who will liaise with the Scientific Committee and coordinate their findings.

Individual centre data will be accessible only to the centre's director and to a national registry steering committee in the event that such a recognized organisation exists for the country (by number – known to each centre only). Data extracts for individual centres are thus not subject to Scientific Committee approval.

Any applications from third country (non-EU) must ensure an adequate level of protection (Directive 95/46/EC (TBC) chapter IV, article 25.1), and must be approved by the Danish Data Protection agency before release of data.

The Scientific Committee will be composed of 5 members:

- 2 elected members from the ECFSPR Steering Group;
- one patient representative ;
- one statistical expert;
- one member of the Executive Committee.

Successful applications are approved by simple majority vote of the Scientific Committee and should be answered within one month of reception. The Steering group will be informed of the Scientific Committee's recommendation and will make a decision on the approval of the data request. This decision will be final.

The title of the project and contact person of all approved applications will be published in the annual activity report.

Applications should be scientific projects headed by individual independent scientists.

All associations with private companies, especially pharmaceutical companies, should be acknowledged in the application.

Applicants will be asked to sign an agreement that data will be used for the sole purpose indicated in the application and then destroyed.

There will be an application fee for data requests. Data extracts will be subject to a fee calculated on hourly cost basis.

4. CTN and ECFSPR cooperation

The CTN Director is appointed as the CTN representative in the ECFSPR Executive Committee. A member of the ECFSPR Executive Committee is appointed ECFSPR representative in the CTN Executive Committee.

Data requests will be previewed by CTN as follows:

- The CTN Executive Committee assesses the requests for data analysis submitted by the Industry. Following approval by the CTN Executive Committee, the question is submitted to the ECFSPR Scientific Committee via a standard request form. The ECFSPR Scientific Committee has 1 week to agree/disagree with this request, explore feasibility and suggest a cost for the analysis.
- Data requests from individual researchers/study groups, for epidemiological studies should be sent directly to the ECFSPR Executive Coordinator by email for distribution to the Scientific Committee.

- There will be an application fee for data requests from the pharmaceutical industry.
- Cost of data extraction/analyses will be calculated for each request depending on the workload.